

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master file no. 2:12-md-02327 MDL
THIS DOCUMENT RELATES TO PLAINTIFFS: DIANE KROPF Case No. 2:12-cv-01202	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE MDL No. 2327

**RULE 26 CASE SPECIFIC EXPERT REPORT OF
RICARDO R. GONZALEZ, M.D.**

I am Dr. Ricardo R. Gonzalez. The medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. In forming my opinions, I have also relied on the general opinions of the experts disclosed in this litigation. I reserve the right to supplement my opinions in this matter as new information becomes available.

I. QUALIFICATIONS, BACKGROUND, AND EXPERIENCE

I am currently a Clinical Assistant Professor of Urology at the Baylor College of Medicine in Houston, Texas. In addition, I am the Medical Director for both the Center for Voiding Dysfunction and Center for Clinical Research. I received my MD degree in 1999 from the Stanford University School of Medicine. Following graduation from medical school, I completed a residency in Urology and a fellowship in Female Urology, Neurology, and Voiding Dysfunction at the Weill Cornell Medical Center. I became board certified in Urology in 2008, and additional board certification in Female Pelvic Medicine and Reconstructive Surgery in 2013. I have published articles and given lectures on the topics of repair of urinary incontinence. I am clinical faculty and instruct medical students and residents for Baylor College of Medicine in Urology and voiding dysfunction. As part of my continuing medical education, I have attended training seminars provided by the American Urological Association, Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction, and manufacturers including American Medical Systems and Boston Scientific. I have served as a cadaver lab preceptor for American Medical Systems and Boston Scientific and am currently involved in the FDA 522 studies related to a

single-incision sling system (Boston Scientific) and biological grafts for prolapse (Boston Scientific). Throughout my career, I have performed hundreds of pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. In addition, I have performed over 80 surgeries dealing with complications related to synthetic mesh slings, including the removal of numerous sling devices. Recently, I have personally examined ten women who had received the ObTape sling and have had complications.

A copy of my CV is attached as Exhibit "A", a list of my testimony for the last four years and Fee Schedule is attached as Exhibit "B." The documents for which I have read and relied on for this report are contained in Exhibit "C" as well as those documents cited throughout this Report and my IME Report is attached as Exhibit "D".

II. MATERIALS REVIEWED AND APPLICABLE METHODOLOGY

In preparation for this report, I reviewed Ms. Diane Kropf's medical records, her deposition testimony, and Plaintiff Fact Sheet ("PFS"), along with the deposition testimony of Drs. Patricia Murray and Charles Beamon. Additionally, I conducted an examination of Ms. Kropf, which was performed in a manner consistent with my standard clinical practices. I have also conducted an extensive review of relevant medical literature and a number of internal documents from mesh manufacturers as they apply to this case. The materials reviewed are more fully set forth in the attached materials reliance list.

In my practice, I determine the cause of the patient's condition based upon an interview with the patient, an examination, a review of her medical records, if available, and discussion of her prior medical history. I then complete a differential diagnosis to determine the cause of a specific injury. Differential Diagnosis is a universally accepted methodology in the United States whereby a physician "rules in" a potential cause and then by elimination, the physician "rules out" the least likely cause. I eliminate potential causes until I reach a cause that cannot be ruled out. I performed this differential diagnosis in arriving at my opinions in this case after reviewing the medical history provided, performing my examination of Ms. Kropf, reviewing her medical history, both verbal and as supplied in the medical records provided, and reviewing her test results, including laboratory tests.

All of my opinions in this case have been reached and are offered to a reasonable degree of medical certainty.

Pelvic Organ Prolapse/Ethicon Prolift

Pelvic organ prolapse (POP) is a condition in which one or more female pelvic organs (bladder, rectum, intestines, and/or uterus) drop or protrude into the vagina as a result of weakened pelvic muscles. This occurs as a result of aging, multiple childbirths, genetic predisposition, frequent heavy lifting, obesity, or constipation.

Treatment plans are based on patient specific factors and the risks and benefits that apply to each unique patient. In some patients, POP is mild and asymptomatic and doesn't require specific therapy; in these situations, the safest treatment option is observation with periodic reevaluations. Additional options include behavioral therapy, pelvic floor exercises, and pessary use. Surgical intervention is used as a last resort for patients with more severe POP who have failed conservative measures. Traditional or native tissue POP repairs involve stitching together the patient's own vaginal, or native tissue to support the vagina and repair POP. This can be done by a transvaginal approach through the vagina or an abdominal approach. In both approaches, stitches are placed under direct vision, the surgeon can see where the stitch is going. Allowing direct visualization reduces the risk of injury to surrounding tissues and pelvic organs, in contrast to the blind insertion of the Prolift System.

The Prolift System

The Prolift System was heavily marketed by Ethicon as a way to increase the durability of POP repair making it superior to traditional non-mesh repairs. This superiority was based upon a misperceived higher failure rate and exaggerated recurrence rates of traditional repairs. Ethicon launched the Prolift System in 2005, it marketed and sold The Prolift System in the United States for over three years prior to obtaining FDA clearance in May of 2008.

The Prolift System comes in three different options; each option has a self-contained kit and procedure. Each kit is similar except for the shape of the mesh and varying surgical components for insertion and retrieval: (1) Gyencare Prolift Anterior Pelvic Floor Repair System – for repair of cystocele (bladder prolapse); (2) Gynecare Prolift Posterior Pelvic Floor Repair System – for repair of rectocele (rectal prolapse); (3) Gynecare Prolift Total Pelvic Floor Repair System – for repair of cystocele, rectocele, and vaginal vault prolapse. While Ethicon's brochures characterize the procedure as "minimally invasive" there is no doubt that the system's implantation constitutes major invasive surgery. The mesh contained in each Prolift system is composed of non-absorbable knitted filaments of polypropylene which resemble their Prolene mesh. Prolift is reported to have a reduced polypropylene diameter fiber which is marketed to be more flexible. The Prolift is identical in its construction to Ethicon's Gynemesh PS and Prolene Soft Mesh. The proposed clinical use for Prolene Soft Mesh is for hernia repair and fascial defect repair.

Complications

Inadequate tissue integration due to inadequate porosity and pore size can result in the development of a rigid scar plate, potentially leading to erosion, nerve entrapment, pain syndromes, dyspareunia, and loss of elasticity and mesh contraction.

Fibrotic bridging and scar plate formation prevent tissue in-growth because there isn't space for the tissue to grow into the mesh as it is intended to do. Mesh wrinkling or curling can also prevent tissue in-growth and may lead to fibrotic bridging.

Vaginal wound healing

Granulation, extrusion, and erosion involve poor vaginal wound healing and represent significant complications with possible permanent symptoms such as pain and infections. Internal Ethicon documents and studies show a post-operative erosion and/or extrusion exposure rate of 13.7% with a 14.1% rate in the US. Over half of these required surgical repair.¹

Complications such as mesh "granulation" or "wound granulation" are associated with poor vaginal healing and possible mesh infection. Symptoms may include, but are not limited to, foul smelling or bloody vaginal discharge, pelvic pain, pelvic discomfort, dyspareunia, and vaginal wound infection.

"Extrusion" or "erosion" are sometimes used interchangeably, but they do differ. It is generally accepted that mesh "extrusion" indicates that the significant inflammation caused by the mesh impairs vaginal wound healing to such a degree as to cause the mesh to be exposed through the vaginal wall. Symptoms of extrusion may include, but are not limited to, pelvic pain, pelvic discomfort, dyspareunia, vaginal wound infection, and foul smelling and bloody vaginal discharge.

Mesh "erosion" differs in that the synthetic mesh has *worn* through the wall of the urethra, or the bladder, rectal, or intestinal walls and can be serious and possibly life-threatening. Symptoms of erosion may include, but are not limited to, pelvic pain, vaginal pain, pain with urination, bladder infection, foul smelling or bloody vaginal discharge, dyspareunia, vaginal wound infections, fever, sepsis, and pelvic organ dysfunction.² Since granulation, extrusion, and erosion likely represent the same problem with poor vaginal healing, they all represent significant complications with possible permanent symptoms such as pain and infections.

Ethicon's internal documents confirmed that they were aware that mesh contracture caused a foreign body response. Despite this knowledge, Ethicon mislead physicians and patients by claiming the Prolift mesh did not noticeably impair wound healing.

Continuous Organ Injury

Ethicon's Device Design Safety Assessment (DDSA) states that the expected risk of vital organ perforation with the Prolift procedure is "*rare*" (1 in 100,000 maximum). However, injury to adjacent pelvic organs have been reported to occur in as many as 3-6.6% of patients implanted with the Prolift System. This is because the female pelvis is packed with multiple anatomic structures in very close spatial proximity and all Prolift trocars are passed blindly. This can result

¹ ETH.MESH.00081035; ETH.MESH.00081083; ETH.MESH.00080954; ETH.MESH.00081006; ETII-01121 – 01122; ETH.MESH.00081000- 00081001.

² Haylen et al., An International Urogynecological Association (IUGA) International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Int Urogynecol J 2011; 22:3-15.

in serious injury to the bladder, pelvic nerves, ureter, and major pelvic blood vessels even with the highest skilled surgeon.

Mesh contraction

Polypropylene surgical mesh is known to contract and shrink when placed in the body. The reported incidence of contraction ranges from 11-20% and can result in infection, chronic vaginal and pelvic pain, vaginal shortening and narrowing, infection, and vaginal fibrosis. Despite knowing of the risk of contraction and the negative consequences associated with contraction, Ethicon failed to provide adequate warning of either.

Foreign body reaction

There is a consensus, based on an abundance of literature, that synthetic meshes with larger pore size, lighter weight, and less surface area, better structural stability and elasticity will have fewer complications and better results. Of all the mesh characteristics, porosity, pore size and stability under load are the most important.³ If the mesh does not allow for incorporation, fibrotic bridging can occur which leads to formation of a rigid scar plate. This can lead to complications such as erosion, extrusion, exposure, contraction, pain, nerve entrapment, dyspareunia, and organ dysfunction.⁴ Ethicon failed to warn of the above listed adverse events.

Degradation

Numerous studies have shown that polypropylene is not biologically inert and is subject to oxidation and degradation. Literature and Ethicon's own studies illustrate that polypropylene meshes degrade, oxidize, crack, and peel in human tissue.⁵ Not only did Ethicon fail to warn physicians and patients that Prolift mesh would degrade in human tissue, but it intentionally misled physicians and patients by asserting that the Prolift system was "not subject to degradation or weakening by action of tissue enzymes."⁶

Pain Syndromes

Chronic pelvic, vaginal, and buttock pain can occur following the implantation of the Prolift system due to several reasons. The blind insertion during implantation can cause injury to the pelvic muscles and anatomy which can result in chronic pain and inflammation. Mesh contraction,

³ Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

⁴ ETH.MESH.00869977 - 00870098; ETH.MESH.02589033 - 02589079; ETH-80645 - 80651; Robinson Deposition 3-13, p 120; Hinoul Deposition 4-5, p165-l; Robinson Deposition 3-13, p129-130; Kirkemo Deposition 4-18, p138.

⁵ Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louise Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: Mater med (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988,ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation "What can we learn from explanted meshes?", Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

⁶ ETH-01777; ETH.MESH.00570955; ETH.MESH.02589066-02589068;

curling, and roping create sharp edges that can result in pain. Nerve trauma, nerve entrapment, and disruption due to excessive scarring and scar plate formation can also cause chronic pain syndromes. Ethicon was aware of these complications but failed to include them in Prolift IFUs.

Sexual dysfunction

Sexual dysfunction can be the result of several factors such as contraction, vaginal shrinkage and/or shortening, scarring, or any other mesh related injuries. Depending on the severity of these factors, outcomes can range from mild discomfort during sexual relations to loss of sexual functioning. The progressive nature of mesh contraction can lead to delayed onset of sexual dysfunction. Internal documents show that Ethicon was aware of this complication and failed to warn physicians and patients.⁷

Stress Urinary Incontinence/TVT

Stress Urinary Incontinence is the involuntary leakage of urine during physical activity that increases abdominal pressure.

Nonsurgical treatments include: (1) pelvic floor exercise, also known as Kegel exercises which improve pelvic floor muscle strength; (2) a removable device known as a pessary which is inserted into the vagina to support the bladder neck; (3) transurethral bulking agents which are injections applied around the urethra; (4) behavior modification such as avoiding activities that trigger leaking; (5) Urinary seals which are adhesive foam pads placed over the urethral opening to prevent leakage; (6) a Urethral insert which is a thin flexible solid tube placed into the urethra to block urine leakage; (7) a bladder neck support device which is a flexible ring with two ridges, once the ring is inserted into the vagina, the ridges press against the vaginal walls supporting the urethra.

Surgical treatments include (1) the Burch Colposuspension, the goal of the Burch procedure is to suspend and stabilize the urethra. This procedure can be done laparoscopically but is not ideal for patients with type III SUI as no hypermobility exists to correct. (2) Pubovaginal sling procedures which have an excellent overall success rate and are a durable cure. A band of autologous, allograft, xenograft, or synthetic material is placed directly under the bladder neck which acts as physical support to prevent descent during physical activity. (3) Midurethral synthetic sling procedure which was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and by creating a midurethral hammock for support during stress events.

Polypropylene mesh (Prolene) contained in the TVT

Several published studies have found a causal relationship between the design of the mesh and incidents of post-operative complications. The polypropylene mesh contained in the TVT has many well-known characteristics that make it unsuitable for permanent implantation in the human

⁷ ETH-80645 – 80651; Walji Deposition 3-8, p398-399; Walji Deposition 3-8, p365-366; Gauld Deposition Rough 4-26, p200; Hinoul Deposition 4-5, p200; ETH.MESH.02017152 2007 Expert Meeting; ETH.MESH.00870466: 2006 Expert meeting; ETH.MESH.01220871 email from Kammerer re: D'Art Conversation with Prof. Jacquetin; ETH.MESH.05448541: Email from Susanne Landgrebe re shrinkage review; ETH-18761: email from Kelly Brown re: Proposal for work with CBAT; ETH.MESH.00130117: Email from Ophelie Berthier re ICS Prolift Abstracts; ETH-80318

vaginal floor, a use for which it was intended. Characteristics making it unsuitable include but aren't limited to: mesh degradation; contraction/shrinkage of encapsulated mesh; deformation of the mesh, fraying, roping, and curling; loss of pore size or pore collapse due to tension; chronic foreign body reactions; infections and bio-films; and fibrotic bridging leading to the formation of scar plates and mesh encapsulation.

It is my opinion, to a reasonable degree of medical certainty, that the polypropylene mesh in the TVT causes a multitude of injuries as a result of the above and other mesh inadequacies. These injuries include but are not limited to: (1) worsening incontinence; (2) chronic and debilitating pelvic pain; (3) worsening incontinence; (4) recurrence; (5) chronic dyspareunia; (6) wound infection and wound healing problems; (7) mesh rejection; (8) ureters injury; (9) formation of pelvic abscesses; (10) the need for additional surgical procedures; (11) pelvic nerve injury; (12) urinary dysfunction; and (13) defecatory dysfunction. Additional injuries include sexual dysfunction and vaginal scarring. In addition to the above injuries, an individual would also have the possibility of suffering multiple erosions that occur their lifetime. Accordingly, Ethicon's TVT mesh is not suitable for the application it was intended for – a permanent prosthetic implant for women suffering from stress urinary incontinence.

Chronic Foreign Body Reaction

Most women who undergo permanent mesh implantation, will have their implant for decades. Bernd Klosterhalfen, a pathology expert for Ethicon informed the company that the reaction between mesh and human tissue can continue for up to 20 years.⁸

The human body has a host defense response to foreign objects placed inside the body. The body's white blood cells are dispatched to attack the foreign object; if the foreign object is not destroyed, the initial inflammatory phase is followed by the chronic inflammatory phase. When permanent surgical mesh is placed inside the body, this foreign body response reacts to the implant. Because polypropylene is a non-absorbable synthetic, it causes a foreign body reaction in the pelvic tissue so there is no way to safely implant the product into this tissue without an increased risk of serious complications. Ethicon's own medical directors have testified that the chronic foreign body reaction from the body's response to mesh can cause a severe inflammatory reaction that can cause chronic pain, erosion, nerve entrapment, dyspareunia and the need for additional surgeries.⁹ One of Ethicon's lead engineers indicated that the foreign body reaction is not transitory; it can decrease over time to a minimum level but it doesn't ever go away.¹⁰ Yet, Ethicon failed to place such a warning in its IFU or communicate this warning to physicians.

It is my opinion to a reasonable degree of medical certainty that polypropylene mesh in the TVT creates a foreign body reaction that can lead to severe complications in patients. Complications may include: 1) the possibility of multiple erosions that can occur throughout one's lifetime; 2) worsening incontinence chronic and debilitating pelvic pain, 3) recurrence, 4) chronic dyspareunia, 5) wound infection, 6) mesh rejection, 7) urinary and defecatory dysfunction, 8) sexual

⁸ ETH.MESH.00870466 (June 6, 2006 Ethicon Expert MeetingMeshes for Pelvic Floor Repair, Norderstedt).

⁹ Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17,184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

¹⁰ ETH.MESH.00211259.

dysfunction, 9) vaginal scarring, 10) injury to ureters, 11) wound healing problems, and 12) possible pelvic abscess formation.

Pore Size and Fibrotic Bridging

Inadequate tissue integration caused by inadequate porosity and pore size can reasonably be expected to result in the development of a rigid scar plate, potentially leading to erosion, nerve entrapment, pain syndromes, dyspareunia, and loss of elasticity and mesh contraction. Small mesh pores that cause fibrotic bridging can turn the mesh into a solid sheet of scar tissue. Fibrotic bridging and scar plate formation prevent tissue in-growth because there isn't space for the tissue to grow into the mesh as it is intended to do. This can cause complications including mesh shrinkage and/or contraction, mesh erosion, nerve entrapment, chronic pain, and dyspareunia.

Ethicon failed to inform physicians and patients that its mesh product was susceptible to fibrotic bridging or that this bridging could lead to the above complications.

Mesh Contraction/Shrinking

Polypropylene surgical mesh is known to contract and shrink when placed in the body. This shrinkage relates to the wound healing process and takes place after the surgical trauma of a foreign body being implanted in the vaginal and pelvic tissue. This contraction/shrinkage is related to the size of the pores and the weight of the mesh. Heavy weight mesh with small pores leads to fibrotic bridging which, as mentioned above, leads to the formation of scar plates. Ethicon knew that heavier weight mesh led to greater contraction/shrinkage. Mesh has been known to contract/shrink 30-50% since 1998.¹¹ Ethicon specifically, knew about the degree of shrinkage by 1998 when its own consultants, Uwe Klinge and Bernd Klosterhalfen noted in published works that polypropylene mesh shrinks 30-50%.¹² Ethicon knew that its mesh would contract/shrink and failed to warn physicians about this possibility or of the painful complications that can result from shrinkage/contracture.

Polypropylene mesh contracts in all patients, and in some patients, this leads to painful complications such as worsening incontinence, chronic dyspareunia, nerve entrapment, wound infection, rejection of the mesh, urinary and defecatory dysfunction, formation of pelvic abscess, chronic pain, recurrence of prolapse, vaginal wall stiffness and scarring, vaginal anatomic distortion, and erosion. When this occurs the mesh cannot be safely and effectively revised or removed.

It is my professional opinion to a reasonable degree of medical certainty that polypropylene mesh used in TVT would shrink/contract and lead to painful complications in women who were implanted with the device.

¹¹ Klinge, U, *Shrinking of Polypropylene Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.

¹² Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969

Prolene Mesh in TVT Degrades over Time

Ethicon first developed sheets of Prolene mesh for the use by surgeons in treating hernias. In claiming the safety and efficacy of their pelvic mesh product to regulatory bodies, Ethicon relied on information and science from the mesh used for hernia repair. The products placement in the vagina creates problems not seen with abdominal placement for hernia treatment. The structural complexities of the vagina along with chemicals found in the vagina and surrounding tissue present unique problems. Numerous studies have shown that polypropylene is not biologically inert and is subject to oxidation and degradation. Studies suggest oxidation of mesh occurs because of the polypropylene and the conditions where it is placed.¹³ This oxidation causes the mesh to become brittle, crack and break apart, to degrade.¹⁴ Studies have shown polypropylene to be chemically reactive; flaking and fissuring leads to degradation and releases toxic compounds into the pelvic tissue. This degradation and release of toxic compounds enhance inflammatory and fibrotic reactions in the tissue of the pelvic floor. Ethicon's own studies illustrate that polypropylene mesh can oxidize, crack, and peel in humans.¹⁵

Polypropylene is vulnerable to highly oxidized substances such as peroxide. It is known to physicians that vaginal tissues are ready sources for peroxide and that the hydrogen peroxide produced by the vaginal species lactobacillus is important in controlling vaginal micro-flora. Additionally, microbial agents such as Candida that can be found inside the normal and abnormal flora of the vagina and pelvic infections such as Bacillus and Pseudomonas, can be a source of biological degradation of polypropylene products.

Significant amount of medical literature concludes polypropylene mesh incites a specific immune response, creating within the vagina a foreign body reaction that directly causes mesh degradation, mesh contraction, fibrosis, vaginal narrowing. It is my professional opinion to a reasonable degree of medical certainty that the mesh used in TVT degrades and that the effect of this degradation in female tissue can lead to greater foreign body reaction, excessive scarring, and enhanced inflammatory response. Ethicon failed to inform physicians about the potential for degradation and the numerous complications that could follow this degradation.

Fraying, Particle Loss, Roping and Curling, Deformation and Loss of Pore Size

Because of the way Ethicon designed TVT mesh, particles separate when stress is put on the mesh. This separation is known as fraying and was described by an Ethicon engineer as a defect due to Ethicon's method of cutting mesh with a blade. This engineer stated that if the cutting method was changed to laser cutting or ultrasonic cutting, they would limit the fraying defect

¹³ Costello C., et al., "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient," Surgical Innovation, 2007, 143:168- 176).

¹⁴ Id.

¹⁵ Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louise Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: Mater med (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988,ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation "What can we learn from explanted meshes?", Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

significantly.¹⁶ In 2001, Dr. Alex Wang, who is known to be one of the most experienced TTVT users in the world, reported problems related to the mesh fraying.¹⁷ By November 2003, Ethicon's medical director, Dr. Martin Weisberg reported 58 complaints of fraying since the product had been introduced only three years earlier in 2000. In a memo dated November 18, 2003, Dr. Weisberg reported observing that the mesh elongates in places, narrows in places, and that the mesh stretching increases the possibility of fraying.¹⁸ A few months later, on February 27, 2004, Ethicon received complaints from surgeons that brittle mesh and particles were falling into the operating field. Despite his observations and the number of fraying complaints, Dr. Weisberg concluded that fraying did not affect the safety or efficacy of the device; therefore, Ethicon determined not to pursue corrective action.¹⁹ By November 2004, one of the top 3 complaints regarding the mesh product included mesh fraying, yet Ethicon maintained it did not affect product safety.²⁰ The complaints about fraying and particle loss continued until by 2010, complaints indicated that pieces of mesh were being found in unopen packages of mesh. Ethicon continued to maintain its products safety.

Additionally, mechanically cut mesh has been shown to curl, rope, and become deformed under tension. Mesh curling and roping increase the risks of complications because they prevent adequate tissue in-growth and may lead to fibrotic bridging and chronic inflammatory events, which increase the risk of complications. Ethicon knew of the hazards of curling, roping, fraying, and inadequate pore size and that these hazards could lead to erosion, recurrence, and pain.²¹

Infections/Bio-films

The vagina is not sterile and can never be completely sterilized. In TTVT, the weave of the mesh produces small interstices that allow bacteria to enter. The bacteria secretes an encasing polysaccharide slime (biofilm) which serves to shield it from the host defenses designed to eliminate them. Consequences of the biofilm increase the foreign body reaction and can result in chronic infections and chronic inflammation as well as erosion, and mesh and scar contracture. The biofilm protects the bacteria surrounding the mesh from the body's host defense response which inhibits the body's ability to fight off infection within the mesh.

When the mesh degrades, polypropylene particles separate from the surface of the mesh fiber, the resulting increase of the surface area provides greater area for the bacteria to adhere to the mesh. This increases the polypropylene's release of toxic compounds which increases the inflammatory reaction. The flaking and cracking that occur while the mesh degrades provides a safe harbor for infectious bacteria. Mesh exposure and erosion cause further exposure to bacteria; these bacteria will adhere to the mesh surface and colonize. It is my opinion to a reasonable degree of medical certainty that TTVT mesh is susceptible to biofilm formation and is thus not suitable for its intended application. Ethicon failed to warn physicians and patients that biofilm could form on the mesh and lead to erosion, recurrent, late infections and necessitate removal of the product.

¹⁶ ETH.MESH.01813975 at 2 (Ex. 3160/3587).

¹⁷ ETH.MESH.03905472 (6/4/01 Emails from Wang, A. re TTVT Recommendation for Ethicon Study of Fraying/Particle Loss).

¹⁸ ETH.MESH.00541379 (11/18/03 Memo from Weisberg re Mesh Fraying for TTVT Devices Inadequate Testing).

¹⁹ ETH.MESH.00541379 (11/18/03 Memo from Weisberg re Mesh Fraying for TTVT Devices Inadequate Testing).

²⁰ ETH.MESH.01813975 (Ex. T-3160 / T-3587).

²¹ ETH.MESH.01218019.

III. CASE-SPECIFIC OPINION

A. Pertinent Medical History

Mrs. Kropf is a 71 year old G3P3003 female. Her surgical history is remarkable for fibromyalgia, arthritis, and asthma. She has had back pain due to a sacral fracture and multiple issues for years. She has had disc spacers from L4-S1 without change in back pain; however, her back pain has nothing to do with the pain she has experienced since the implant of her vaginal mesh.

In May 2008, Mrs. Kropf presented to Dr. Murray with a second degree cystocele, second degree uterine prolapse, and vaginal mucosal atrophy. Less than one year later, in March 2009, Mrs. Kropf reported problems with urinary incontinence.

On April 5, 2010, Mrs. Kropf had a third degree cystocele and second degree rectocele, and underwent a vaginal hysterectomy, bilateral salpingo-ophorectomy, anterior vaginal wall repair using Gynemesh Prolift, placement of a TVT-O, and an enterocele repair. This procedure was performed by Dr. Patricia Murray without any reported complications.

On July 3, 2012, Mrs. Kropf presented to the Gynecology Associates of Fredericksburg with urinary frequency, dysuria and atrophic vaginitis. A pelvic exam performed on March 28, 2013 confirmed exposed mesh on the left anterior vaginal wall. At this time, estrogen vaginal cream was prescribed for the erosion; however, Ms. Kropf still presented with exposed mesh on September 24, 2013.

Due to exposed mesh, Mrs. Kropf continued to experience persistent pelvic pain and urinary symptoms. As a result, Dr. Charles Beamon operated on Mrs. Kropf on November 11, 2014. During this procedure, Dr. Beamon removed a piece of mesh from the left side of Mrs. Kropf's vaginal floor.

B. Independent Medical Examination

I conducted a medical examination on Ms. Kropf on November 16, 2015 and she described the symptoms of vaginal and abdominal pain, dyspareunia, and complications secondary to mesh erosion. Abdominal examination: the liver and spleen appear to be normal, abdomen is obese and distended. Abdominal scars are well-healed. No abdominal masses or tenderness noted. No CVA tenderness of the left or right kidneys.

No cystocele is present. A grade 2 rectocele is present. No splinting to empty bowels. Cervix and Uterus were surgically absent. She has a vaginal mesh extrusion of the left proximal Prolift arm and cuff. A 5mm x 10mm area is exposed and friable; this bleeds easily. The lateral attachment into the pelvic side wall is moderately tender to palpation. There is less banding on the right, but it is also compatible with likely mesh contracture; no right side banding has extruded. She has significant atrophy around her introitus, especially posteriorly.

Subsequent to my medical examination and thorough review of Ms. Kropf's medical records, I came to the following conclusions to a reasonable degree of certainty: vaginal and abdominal pain, dyspareunia, and complications of multiple erosions secondary to the placement of the Prolift.

It is my recommendation that Ms. Kropf would benefit from: excision of the extruded mesh and tight mesh contractures of the proximal Prolift arms. I also recommend that she comply with the topical estradiol therapy that was prescribed, as it will likely improve her atrophy, which will help her heal better from any planned mesh revision.

C. The Ethicon Products Caused Ms. Kropf's Injuries

I am familiar with the medical complications that are generally associated with pelvic repair surgery. I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by transvaginal mesh and sling implants. Among the most common complications associated with polypropylene mesh implants that I am personally familiar with are scar bands or scar plates in the vagina, vaginal shortening, vaginal stenosis, erosion of mesh into tissues or organs, nerve entrapment as a result of mesh scarring and fibrotic bridging, pelvic pain, scarring in the vagina, scarring in the pelvic floor, permanent or chronic dyspareunia, stress urinary incontinence, urge incontinence, urinary retention, constipation or fecal incontinence, encapsulation of mesh (mesh covered in thick scar tissue), chronic inflammation of the tissues or organs, and deformed, curled, folded, wrinkled, degraded and fragmented mesh after removal.²² Medical literature published also reports on these types of complications.²²

In my practice, I determine the cause of the patient's condition based upon an interview with the patient, an examination, a review of her medical records, if available, and discussion of her prior medical history. I then complete a differential diagnosis to determine the cause of a specific injury. Differential Diagnosis is a universally accepted methodology in the United States by practicing physicians in my field, whereby a physician "rules in" a potential cause and then by elimination, the physician "rules out" the least likely cause.²³ I then eliminate potential causes until I reach a cause that cannot be ruled out. I have performed this differential diagnosis after reviewing the medical history provided, performing my examination of Ms. Kropf, reviewing her medical history, both verbal and as supplied in the medical records provided, and reviewing her test results, including laboratory tests. I performed this differential diagnosis to rule out potential likely causes of her injuries. I also ruled out potential comorbidities and potential causes of the injuries and symptoms Ms. Kropf complained of.

My review of Ms. Kropf's medical records revealed that the mesh implantation procedures were completed within the standard of care. In reviewing Ms. Kropf's medical records, I found no deviation from the standard of care provided by Drs. Murray or Beamon.

²² Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair*, Surg Technol Int. 2014, 24:217-24.

²³The American Heritage (2007)

In my judgment, to a reasonable degree of medical and scientific certainty, the injuries suffered by Ms. Kropf, including vaginal and abdominal pain, dyspareunia, and complications due to multiple erosions of the mesh, are a direct result of shrinking, contraction, and scarring of the mesh products and their inadequate design as described above, including the foreign body reaction they elicit.

D. Ethicon Failed to Warn Ms. Kropf and Her Implanting Surgeon of Known Serious Risks of Complications Resulting from Prolift and TVT

I have reviewed the Information for Use for both the Prolift and the TVT, and it is clear that Ethicon failed to provide the proper warnings associated with its products. The risks and adverse reactions that Ethicon knew and failed to report include, but are not limited to, Ethicon's inadequate testing of the product with no long-term studies, inadequate guidance for providing the proper tension, insufficient data to support this use of Prolene mesh, insufficient statements that its mesh was associated with only a slight and transient inflammatory response when Ethicon knew the inflammatory response was significant in some patients, insufficient warnings related to mesh degradation, incomplete warnings related to dyspareunia for sexually active women, and insufficient warnings about the contraction of the mesh that can cause pain among other complications.

I have reviewed the entirety of Dr. Murray's testimony, which informs my opinion of the types of information that Ethicon failed to warn her of. Specifically, Ms. Kropf's implanting physician, Dr. Murray, testified that, if she knew the Prolift mesh did not remain soft and pliable, and the mesh would become rigid and hard in a number of patients, it would have impacted her decision to use the Prolift product in Ms. Kropf.²⁴ She further testified that if she had known the implant of the Prolift would cause a chronic inflammatory reaction in more than 5% of the patients, she would not have used the Prolift.²⁵ Dr. Murray also testified that if she had known that mesh exposure were considered common by Ethicon employees, it would have impacted her decision to use the products.²⁶

Furthermore, Ethicon failed to warn Dr. Murray that the Prolift should not be used on sexually active patients and that a hysterectomy should not be performed at the same time as implanting the Prolift, and Dr. Murray testified that if she had been informed of these issues, she would not have used the Prolift.²⁷

These risks, adverse reactions, and warnings, as well as the clinical consequences, should have been clearly stated in the IFU so that Dr. Murray would be fully informed, and so Ms. Kropf could have been properly informed.

²⁴ Deposition of Dr. Murray, 112:13-22.

²⁵ Id. at 118:23 – 119:20.

²⁶ Id. at 128:6-21.

²⁷ Id. at 129:15 – 130:19; 133:8-134:3.

CONCLUSION

To a reasonable degree of medical certainty, based on Ms. Kropf's medical records, the depositions of her and her physicians, and my examinations of Ms. Kropf, it is my opinion that Ms. Kropf's injuries, including vaginal and abdominal pain, dyspareunia, and complications due to multiple erosions of the mesh secondary to the placement of Gynecare Prolift and TVT-O were caused by the shrinking, contraction, and scarring of the mesh and the defective design of the products as previously described, including the foreign body reaction they elicit.

My opinions in this case are based on my background, training, and experience as a clinician, as well as the materials I have reviewed in this case. Additionally, in forming my opinions, I have relied on the general opinions disclosed in this litigation, as referenced throughout. My opinions regarding the cause of the injuries suffered by Ms. Kropf are expressed to a reasonable degree of medical certainty and are based on reasonable medical probability and scientifically reliable evidence.

I have conducted my own review of the pertinent medical literature independently verifying the opinions reviewed and expressed herein. I reserve the right to supplement my opinions in this matter as necessary.

Dated this 1 day of February, 2016.



Ricardo Gonzalez, M.D.

EXHIBIT

A

6560 FANNIN SUITE 2030 • HOUSTON, TX 77030
 OFFICE (713)790-9779 • FAX (713)794-0719

RICARDO R. GONZÁLEZ, M.D.

Education	Stanford University School of Medicine, Stanford, CA	M.D. 1999
	Occidental College, (Honors in Psychobiology) Los Angeles, CA	A.B. 1994
	University of North Texas Denton, TX	1990 - 1992
Professional Specialties (Board Certification)		
	American Board of Urology, Diplomate	2008
	Female Pelvic Medicine and Reconstructive surgery (FPMRS)	2013
	American Board of Urology and American College of Obstetrics and Gynecology	
Honors		
	America's Top Urologists List, Consumers' Research Council of America	2007- 2013
	Patient's Choice Award	2009- 2013
	Texas Super Doctors, Rising Star Award	2012- 2013
	Top Doctors <i>Texas Monthly</i> award based on peer review	2013
	Doctor's Choice Award, Top Physicians in Houston One of ten urologists chosen by peers by Health & Fitness Magazine	2009
	Ferdinand Valentine Fellow for Research in Urology, New York Academy of Medicine	2005 - 2006
	Kidney and Urology Foundation of America Research Fellowship	2005 - 2006
	American Urological Association, Gerald P. Murphy Scholar	2005 & 2006
	Cornell Alumni Council Distinguished House Staff Award, Urology New York Presbyterian Hospital-Cornell (biennial award)	2004
	Jack Lapides Prize in Neurourology and Urodynamics, Honorable Mention	2004
	Ferdinand Valentine Essay Contest, New York Academy of Medicine Laboratory Research Honorable Mention	2004

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RR González 3

Research Assistant, Mayo Vaccine Research Group, Mayo Clinic
Rochester, MN Summers of 1995 and 1996
PI: Gregory A. Poland, M.D., Founder and Director of the Mayo Vaccine Research Group, and Associate Director of the General Clinical Research Center, Mayo Clinic and Foundation.
Subject: Investigating the measles vaccination status, measles antibody seroprevalence, and immunogenetic typing of Hispanic migrant farmworkers.

Research Assistant, Division of Neurosurgery, Stanford University
Stanford, CA 1994 - 1995
PI: Gary K. Steinberg, M.D., Ph.D., Chair of the Division of Neurosurgery, Stanford University School of Medicine
Subject: Elucidating the metabolic mechanisms of hypothermic neuroprotection in a model of focal ischemia in the rat brain.

Honors Thesis Research, Department of Psychobiology, Occidental College
Los Angeles, CA 1993 - 1994
PI: Nancy K. Dess, Ph.D., Professor of Psychobiology, Occidental College.
Subject: Establishing the differences in the development of activity-based anorexia in two lines of rats differing in general metabolic efficiency.

Richter Fellow, Universidad Autónoma de Madrid, Hospital Del Niño Jesús
Madrid, Spain Summer 1993
PI: Jesús Argente, M.D., Ph.D., Head, Division of Pediatric Endocrinology and Metabolism, Hospital Del Niño Jesús.
Subject: The effectiveness of orally-administered Growth Hormone (GH) Releasing Peptide-2 at stimulating GH release in children.

Publications

Journal Articles

Hueber PA, Liberman D, Tal BZ, Woo H, Hai M, Te AE, Lee R, Rutman M, **González RR**, Barber N, Al-Hathal N, Al-Aoud T, Trinh QD, Zorn ZC. 180W vs 120W lithium triborate photoselective vaporization of the prostate for benign prostatic hyperplasia: a global, multi-center comparative analysis of peri-operative treatment parameters. *Urology*, in press 2013 URL-D-13-00280R1

Hollander AB, **González RR**. Evaluation and management of urgency and urge urinary incontinence in men. *Current Bladder Dysfunction Reports*; Volume 7, Number 3 (2012), 230-234.

Goh A, **González RR**. Photoselective laser vaporization prostatectomy versus transurethral resection of the prostate: A Cost Analysis. *JUrol*, 2010 April; 183(4): 1469-73.

Saini R, **González RR**, Te AE. Chronic pelvic pain syndrome and overactive bladder: the inflammatory link. *Curr Urol Rep*. 2008 Jul;9(4):314-9.

RR González 4

Kaplan SA, **González RR**. Phosphodiesterase type 5 inhibitors for the treatment of male lower urinary tract symptoms. *Rev Urol* Spring 2007; 9(2): 73-77.

Kaplan SA, **González RR**, Te AE. Combination of alfuzosin and sildenafil is superior to monotherapy in treating lower urinary tract symptoms and erectile dysfunction. *Eur Urol*. 2007 Jun; 51(6):1717-23.

González RR, Te AE. Chronic Prostatitis/Pelvic Pain Syndrome: a bladder dysfunction? *Curr Bladder Dysfunction Rep* Mar. 2007; 2(1): 55-59.

González RR. Advances in Female Urology. *The Urology Report* Winter 2007 ; 1(1): 10-15.

Lee R, Al-Ahmadi HA, Boorjian SA, **González RR**, Felix Badillo, Rueter VE, Steckel J. A case of incidental adrenocortical oncocytoma. *Nat Clin Pract Urol* Nov 2006; 3(11): 618-21.

Ng, CK, **González RR**, Te AE. Refractory overactive bladder in men: update on novel therapies. *Curr Urol Rep* Nov. 2006; 7(6): 456-61.

Lee R, **González RR**, Te AE. The evolution of photoselective vaporization prostatectomy (PVP): advancing the surgical treatment of benign prostatic hyperplasia. *World J Urol*. 2006 Sep; 24(4): 405-9.

González RR, Kaplan SA. First line BPH treatment: is there a particular patient profile for a particular treatment? *World J Urol*. 2006 Sep; 24(4): 360-6.

González RR, Kaplan SA. Tadalafil for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Expert Opin. Drug Metab. Toxicol.* 2006 Aug; 2(4): 609-17.

González RR, Te AE. Is there a role for urodynamics in chronic nonbacterial prostatitis? *Curr Urol Rep* July 2006; 7(4): 335-38.

Monoski M, **González RR**, Sandhu JS, Reddy B, Te AE. Urodynamic predictors of outcomes with photoselective laser vaporization prostatectomy in patients with benign prostatic hyperplasia and preoperative retention. *Urology* 2006; 68(2): 312-7.

Monoski M, **González RR**, Thomas A, Goldstein M. Arteriovenous malformation of the scrotum causing virtual azoospermia. *Urology* 2006; 68(1): 203.e5-6.

González RR, Te AE. The role of urodynamics in chronic nonbacterial prostatitis. *Curr Prostate Rep* April 2006; 4(1): 41-4.

RR González 5

Sandhu JS, Nb CK, **González RR**, Kaplan, SA, Te AE. Photoselective laser vaporization prostatectomy in men receiving anticoagulants. *J Endourol* Dec 2005; 19(10): 1196-8.

Reddy BN, **González RR**, Te AE. The implications of cytokines in chronic prostatitis and chronic pelvic pain syndrome. *Curr Prostate Rep* Nov 2005; 3(4): 189-94.

Shelton JB, Barocas DA, Conway F, Hart K, Nelson K, Richstone L, **González RR**, Raman JD, Scherr DS. Prostate-specific antigen screening in a high-risk population: lessons from the community and how they relate to large-scale population-based studies. *Urology*. 2005 May; 65(5): 931-6.

González RR, Fong T, Belmar N, Saban M, Felsen D, Te AE. Modulating bladder neuroinflammation: RDP58, a novel anti-inflammatory peptide, reduces inflammation and nerve growth factor production in experimental cystitis. *J Urol* 2005 Feb; 173(2): 630-4.

González RR, Te AE. Chronic Prostatitis and sensory urgency: whose pain is it? *Curr Urol Rep*. 2004 Dec; 5(6): 437-41.

González RR, Te AE. Overactive bladder and men: Indications for anticholinergics. *Curr Urol Rep* 2003 Dec; 4(6): 429-435.

González RR, Te AE. How do transurethral needle ablation of the prostate and transurethral microwave thermotherapy compare with transurethral prostatectomy? *Curr Urol Rep* 2003 Aug; 4(4):297-306.

Multimedia

González RR. Laser Treatments for the Advanced Prostate. Featured interview for international news broadcast, "Primer Impacto", Univision April 19, 2008.

González RR, Staskin DR. Editor and correspondent at the Society for Urodynamics and Female Urology 26th Annual Meeting. May 21 2005. www.urotoday.org

González RR, Te AE. Photoselective vaporization of the prostate with the 80 watt quasicontinuous KTP laser for the treatment of benign prostatic hyperplasia. Video. American College of Surgeons, Cine Clinics, Clinical Congress, October 12, 2004, New Orleans, LA.

Book Chapters

Lee R, Sandhu J, **González RR**, Te AE. Laser prostatectomy. *Smith's Textbook of Endourology*. Eds. Smith AD and Badlani GH. Hamilton, ON: BC Decker; 2006 in press.

Schwartz MJ, **González RR**, Weiss JP, Blaivas JG. Neurogenic Bladder. *Fast Facts Urology Highlights 2005-2006*. Ed. Shah J. London, UK: Healthpress Ltd.; 2006 in press.

RR González 6

González RR, Tyagi R, Te AE. Neurological Disorders. *Textbook of Female Urology and Urogynaecology*. Eds. Cardozo L and Staskin D. London: Martin Dunitz, Ltd.; May 2006.

González RR, Lee R, Sandhu J, Te AE. Laser prostatectomy. *Atlas of the Prostate, Third Edition*. Eds. Scardino PT and Slawin KM. Philadelphia: Current Medicine, Inc.; December 2005.

Presentations

Shy M, Khavari R, Stewart J, **González RR**, Fletcher S. Incontinence outcomes after colpocleisis for symptomatic pelvic organ prolapse. *Research to be presented at the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) in February 2012 in Las Vegas, NV.*

Mercado MA, Dunkin BJ, **González RR**. Proving face, content, and construct validity for a photoselective vaporization of prostate (PVP) simulator. *Research to be presented as a podium presentation at the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) in February 2012 in Las Vegas, NV.*

Shy M, Gerald T, Sathyamoorthy K, Lee A, **González RR**. Photoselective Laser Vaporization of the Prostate (PVP) prior to radiation is safe and effective at treating symptomatic benign prostatic hyperplasia (BPH) in men diagnosed with prostate cancer. Accepted for podium presentation at American Urologic Association Annual Meeting in Atlanta, Georgia; May 22, 2012.

González RR. "Take Home Messages" for BPH and Male Lower Urinary Tract Symptoms. Plenary presentation at the American Urologic Association Annual Meeting in Atlanta, Georgia; May 23, 2012.

Khavari R, Sathyamoorthy K, **González R**, Fletcher S. Impaired detrusor contractility and the treatment of female stress incontinence. Presented at Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction; New Orleans, LA, March 1, 2012.

González RR. Photoselective Laser Vaporization of the Prostate, Standardizing Surgical Technique. Surgical video presentation, World Congress of Endourology; Kyoto, Japan, December 2, 2011.

Goh H, Knerr M, Su L, David SG, **González RR**. Photoselective Laser Vaporization Prostatectomy Versus Transurethral Resection of the Prostate: A Cost Analysis. *J Urol* 2009 April, 181(4): 766.

González RR. Will TURP die? Representing laser prostatectomy in live debate with surgeries. Congresso Paulista de Urologia; Sao Paulo, Brazil, September 4, 2010.

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González RR. State of the art treatment for the enlarged prostate: Lithium Boride 120 W laser prostatectomy. Presented with live surgeries at the 25th Annual Meeting, Korean Andrological Society; Busan, Korea, April 3, 2008.

Sander JC, Avila D, **González RR.** Safely integrating new technology into urological practice: evaluation of a training model for Photoselective Laser Vaporization Prostatectomy (PVP). Presented at the 25th Annual Meeting, Korean Andrological Society; Busan, Korea, April 3, 2008.

González RR. Incorporating new technology into your developing practice: experience with the GreenLight HPS. Presented at American Urological Association Annual Meeting, Anaheim, CA, May 21, 2007.

González RR. Advances in the treatment of the enlarged prostate: a focus on laser prostatectomy. Presented at the Society for Urologic Nurses and Associates (SUNA) regional meeting, Houston, TX, April 18, 2007.

González RR. Photoselective Laser Vaporization Prostatectomy (PVP): Technique and Outcomes. Presented at Baylor Urology Grand Rounds, the Methodist Hospital, Houston, TX, Mar 28, 2007.

Te AE, Yang JH, **González RR**, Reddy BN, Zhou X, Madhu M, Kaplan SA. Safety and efficacy of photoselective laser vaporization of the prostate for benign prostatic hyperplasia in men over 80 years. Presented at the Western Section AUA Annual Meeting, Maui, HI, Oct 22, 2006.

Te AE, **González RR**, Reddy BN, Kaplan SA. Photoselective laser prostatectomy-vaporization incision technique for large prostates. Presented at the Western Section AUA Annual Meeting, Maui, HI, Oct 22, 2006.

Kaplan SA, **González RR**, Ogiste J, Te AE. Combination of an alpha-blocker, alfuzosin SR and a PDE-5 inhibitor, sildenafil citrate, is superior to monotherapy in treating lower urinary tract symptoms (LUTS) and sexual dysfunction. Abstract #1638 *J Urol* 2006, 175(4): 528.

Kaplan SA, Kaplan JD, **González RR**, Te AE. The use of a voiding diary to evaluate urinary frequency and nocturia is a better indicator than the IPSS in assessing alpha-blocker efficacy in men with lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH). Abstract #1359 *J Urol* 2006, 175(4): 438.

González RR, Reddy B, Chen J, Staskin DR, Te AE. Effects of short-term estrogen deprivation on experimental bladder inflammation. Abstract #189 *J Urol* 2006, 175(4): 61-2.

González RR, Reddy BN, Sandhu JS, Kaplan SA, Te AE. High-power KTP photoselective laser vaporization prostatectomy (PVP): the Cornell experience. *Lasers in Surgery and Medicine* 2006 38 (S18): 57-58.

RR González 8

González RR. Combination medical therapy for BPH. Panelist at the Society for Female Urology and Urodynamics Annual Meeting, Grand Bahamas, February 22-25, 2006.

González RR, Reddy BN, Sandhu JS, Kaplan SA, Te AE. High-power KTP photoselective laser vaporization prostatectomy: the New York Presbyterian experience. Presented at the Society for Female Urology and Urodynamics Annual Meeting, Grand Bahamas, February 22-25, 2006.

El-Hakim A, **González RR**, Beneck D, Tewari AK. Sub-detrusor, pre-seminal vesicle fascia: characterization and composition. Presented at the World Congress of Endourology, Amsterdam, Netherlands, Aug 24, 2005.

Monoski MA, Sandhu JS, **González RR**, Te AE. Urodynamic predictors of success with photoselective laser vaporization prostatectomy in patients with benign prostatic hyperplasia and preoperative retention. Abstract #1305 *J Urol* 2005, 173(4): 354.

Te AE, Sandhu JS, Reddy B, Ng CK, **González RR**, Kaplan SK. The first 200 patients treated with high-power KTP photoselective laser vaporization prostatectomy: the New York Presbyterian experience. Abstract #1561 *J Urol* 2005, 173(4): 423.

Sandhu JS, Isom-Batz G, **González RR**, Sherntov M, Te AE, Eilber K. Transurethral resection of the prostate following radiation therapy for prostate cancer. Presented at the Society for Urodynamics and Female Urology, Orlando, FL, February 24-27, 2005.

Sandhu JS, Ng CK, **González RR**, Kaplan SK, Te AE. Photoselective vaporization Prostatectomy in anticoagulated men. Presented at the World Congress of Endourology, Mumbai, India, *J Endourol*. 2004, Nov; 18 Suppl 1: A3-246.

Sandhu JS, Ng CK, **González RR**, Kaplan SK, Te AE. High-power KTP photoselective laser vaporization prostatectomy in men with large prostates. Presented at the World Congress of Endourology, Mumbai, India, *J Endourol*. 2004, Nov; 18 Suppl 1: A3-246.

González RR, Belmar N, Fong T, Te AE. Modulating the bladder neuroinflammatory loop: RDP58, a novel anti-inflammatory peptide, reduces nerve growth factor production in murine models of inflammatory cystitis. Presented at the Lapidés Award Ceremony AUA Annual Meeting, May 8-13, 2004.

Te AE, Sandhu JS, Ng C, **González RR**, Egan C, Kaplan SA. High-power photoselective laser vaporization prostatectomy (PVP) versus transurethral electrovaporization of the prostate (TVP) for the treatment of benign prostatic hyperplasia (BPH): a prospective comparative trial. Abstract #1527 *J Urol* 2004, 171(4): 402.

RR González 9

Sandhu JS, Ng C, **González RR**, Kaplan SA, Te AE. High-power KTP photoselective laser vaporization prostatectomy in men with large prostates: The New York Presbyterian series of 64 patients. Abstract #1522. *J Urol* 2004; 171(4): 400.

González RR, Belmar N, Tesi RJ, Fong T, Te AE. RDP58, a novel anti-inflammatory peptide, inhibits inflammatory histopathology and cytokine production in a mouse model of experimental cystitis. Basic Science Research Award for podium presentation at the Research Insights into Interstitial Cystitis Symposium of the NIDDK, Oct. 30- Nov. 1, 2003; Alexandria, VA.

Iyer S, **González RR**, Zhao J, Lazarov M, Welihinda A, Buelow R, Te AE, Fong T. RDP58, a rationally designed peptide, inhibits multiple forms of pathogenic inflammation through the inhibition of p38MAPK and JNK. *Peptide Revolution: Genomics, Proteomics & Therapeutics*, podium presentation Annual Meeting of American Peptide Society, July 2003, Boston, MA.

González RR, Fong T, Felsen D, Te AE. The effect of DMSO on bladder inflammation in a murine model of acute inflammatory cystitis. Abstract #268. *J Urol* 2003; 169(4): 68-69.

González RR, Fong T, Felsen D, Te AE. RDP58 reduces bladder inflammation in a murine model of acute inflammatory cystitis. Abstract #264. *J Urol* 2003; 169(4): 69-70.

González RR, Fong T, Felsen D, Te AE. The effect of RDP58 and DMSO on inflammation in a murine model of acute inflammatory cystitis. Presented at the Society for Female Urology and Urodynamics Annual Meeting, April 26, 2003, Chicago, IL.

González RR, Coleman JA, Poppas D. Laparoscopic heminephroureterectomy in infants and children with renal duplication: a description of technique and review of outcome. Presented at the Ferdinand Valentine Essay Contest, 2002, New York, NY.

González RR, Camacho LE, Poland GE. Lessons learned in using cultural sensitivity in recruiting Hispanic migrant farmworkers and their dependents into clinical research. (Abstract) *Journal of the Association for Academic Minority Physicians* 1997; 8 (4): xvii.

González RR, Berg HZ, Ledo R, Jacobson RM, and Poland GA. Measles vaccine delivery in children of Hispanic migrant farmworkers: failure to meet the Healthy People 2000 immunization goal. Presented at the 30th National Immunization conference, April 9, 1996, Washington, D.C.

Poland GA, **González RR**, Berg H, Ledo R, Jacobson RM, Marshal J, Rogers S, and Riggs BL. Recruitment of Hispanic migrant farmworkers into

RR González 10

clinical studies; lessons learned. Submitted to NIH GCRC Program to supplement grant M01-RR00585.

González RR, Maier CM, Ahern K. vB., Steinberg GK. A novel technique for regionally quantifying adenylate levels in the rat brain. Poster presented at the Thirteenth Annual Stanford Medical Research Symposium, May 3, 1996, Palo Alto, CA.

Maier CM, Ahern K. vB., **González RR**, Steinberg GK. Effects of mild and moderate hypothermia on neurologic outcome, infarct size, and adenylate levels following transient MCA occlusion in rats. *Society of Neuroscience Abstracts*. 1995; 22: 1030.

González RR, Dess, NK. The effectiveness of a competing-response model in developing activity-based anorexia in two lines of rats differing in "emotionality". Poster presented and abstract published in the *Proceedings of the Annual Conference of the Society for the Advancement of Chicanos and Native Americans in the Sciences*, March 1994, Chicago, IL.

**Teaching
And Education**

Surgical Proctor and Trainer for Photoselective Laser Vaporization Prostatectomy with GreenLight from 2005 to today. Invited lectures and live surgical training including Baylor College of Medicine, University of Southern California, Kaiser Permanente Southern California and Irvine, University of California San Francisco, Stanford, University of Texas Medical Branch Galveston, Cedars Sinai, Argentina, Venezuela, Brazil, Mexico, Costa Rica, Columbia, Ecuador, Bolivia, Panama, Japan, South Korea and Taiwan.

Faculty Member, Benign Prostatic Hyperplasia (BPH) Courses, 2005- 2013 American Medical Association Continuing Medical Education Courses.

Responsible for syllabus and sessions on minimally invasive surgical options for BPH and laser safety, including lectures and laboratory.

Spanish-Language Editor [volunteer], American Urological Association's patient education web site (www.UrologyHealth.org) Topics include: bladder trauma, overactive bladder, enlarged prostate, and kidney stones.

Cornell Resident Panelist, American College of Graduate Medical Education (ACGME) Cornell-Columbia Outcomes Project for Systems-Based-Practice. Developed case scenarios to present at various departments' grand rounds to test the six ACGME competencies.

Coordinator and Presenter, Cornell-Pfizer Urology Symposium. Developed to review general urology for pharmaceutical executives and sales representatives. New York, NY. November 8, 2003.

RR González 11

	Teaching Assistant, Department of Anatomy, Stanford University School of Medicine.	1995
	Teaching Assistant, Algebra II, Summer Opportunities for the Academically Ready (SOAR; Program for talented, underprivileged minorities), at the University of North Texas.	1991
Administrative Activities	Director (founding), Center for Voiding Dysfunction Houston Metro Urology	2008 - present
	Founding Member, Cornell Center for Pelvic Pain	2004 - 2006
	Chief Resident, Department of Urology	2004 - 2005
	President, Stanford Medical Students Association	1996 - 1997
	Member, Steering Committee on LCME Reaccreditation	1996 - 1997
	Member, Stanford's Council on Diversity -to restructure affirmative action program	1996 - 1997
	Recruiter, File Reviewer, and Interviewer for Stanford Medical School Office of Admissions.	1995 - 1997
	State Representative (Stanford), California Chicano Medical Student Association	1994 - 1995
Memberships	American Urological Association Society for Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction International Urogynecological Association Endourological Society American Society of Reproductive Medicine American Medical Association	
Interests	Farming, spinning, and travel.	
Personal	Fluent in Spanish. Married (Marcela) with three sons Texas State License: M3237	

**Exhibit
B**

6560 FANNIN SUITE 2030 * HOUSTON, TX 77030
OFFICE (713) 790-9779 * FAX (713) 794-0719

RICARDO R. GONZALEZ, M.D.

FEE SCHEDULE

\$500 per hour for review of documents or meetings
\$6,000 per half-day deposition or trial testimony
\$10,000 per full-day deposition or trial testimony

PREVIOUS TESTIMONY

June 2012: Quick v. Mel Dugan, et al.
Alabama
Retained by Lorance & Thompson
Defense witness

November 2014: White Ross v. C.R. Bard
Villnave v. C.R. Bard
Mueller v. C.R. Bard
Mitchell v. C.R. Bard
Messer v. C.R. Bard
Douglas-Jones v. C.R. Bard
Groover v. C.R. Bard
Gruman v. C.R. Bard

EXHIBIT
“C”

PROLIFT RELIANCE LIST

MEDICAL PUBLICATIONS:

Abdel Fattah I, Ramsey I. Retrospective multicentre study of the new minimally invasive mesh repair devices for POP. BJOG. 2008 Jan; 115(1):22-30.

Abed H, Rahn D, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011 Jul;22(7):789-98.

Adedipe et al., Perioperative and immediate postoperative outcomes of Gynecare Prolift pelvic floor repair system in a predominantly obese population. Int Urogynecol J 2009; 20(Suppl 3):S241-S491(S424).

Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair. Surg laparosc endosc percutan tech 2007, 17:91-94.

Altman D, Falconer C. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. Obstet Gynecol. 2007 Feb; 109(2 Pt 1):303-8.

Altman D, Tapiola V et al. Short-term outcome after transvaginal mesh repair of POP. Int Urogynecol J (2008) 19:787-793.

ALTMAN D, Vayrynen T, Engh M: Anterior colporrhaphy versus transvaginal mesh for pelvic organ prolapse. N Engl J Med. 2011 May 12;364(19):1826-36.

Altman D, Elmer C Kiiholma P et al: Sexual dysfunction after trocar-guided transvaginal mesh repair of pelvic organ prolapse. Obstet Gynecol. 2009 Jan;113(1):127-33.

Altman D, Zhang A, Falconer C: Innervation of the rectovaginal wall in patients with rectocele compared to healthy controls. Neurourology and Urodynamics 25:776-781.

Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1: 15-21.

Amrute KV, Eisenberg ER. Analysis of outcomes of single polypropylene mesh in total pelvic floor reconstruction. Neurourology and Urodynamics 26:53-58, 2007. [uses AMS apogee and perigee]

Argirovic RB, Gudovic AM et al, Transvaginal repair of genital prolapse with polypropylene mesh using tension-free technique. Eur J Obstet Gynecol Reprod Biol. 2010 Nov; 153(1):104-7.

Aungst MJ, Friedman EB. De novo stress incontinence and pelvic symptoms after transvaginal mesh repair. Am J Obstet Gynecol. 2009 Jul;201(1):73.e1-7.

Bader G, Fauconnier A, Roger Net al: Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh. Technique and results. Gynecologie Obstetrique & Fertilite 32 (2004) 280-284.

Baessler K, Maher C: Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits. Curr Opin Obstet Gynecol. 2006 Oct;18(5):560-6.

Bafghi A, Lannelli A, Verger S et al: Transvaginal repair of genital prolapse with Prolift: evaluation of safety and learning curve. J Gynecol Obstet Biol Reprod (Paris). 2009 Feb;38(1):77-82. Epub 2008 Nov 25.

Barber M, Brubaker L, Nygaard, I et al. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol. 2009 September; 114(3): 600-609.

Bekker, et al., Trasurethral and suprapubic mesh resection after Prolift bladder perforation: a case report. Int Urogynecol J 2010; 21:1301-1303.

Bellon J, Honduvilla N, Jurado Fetal: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul;22(14):2021-4.

Benhaim Y, de Tayrac R, Deffieux X, Gervaise A et al: Treatment of genital prolapse with a polypropylene mesh inserted via the vaginal route. Anatomic and functional outcome in women aged less than 50 years. J Gynecol Obstet Biol Reprod (Paris). 2006 May;35(3):219-26.

Berrocal J, Clave H, Cosson M (The TVM Group) et al: Conceptual advances in the surgical management of genital prolapse. J Gynecol Obstet Biol Reprod 2004; 33:577-587.

Bhandari M, Busse J, Jackowski D et al: Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. CMAJ. 2004 Feb 17;170(4):477-80.

Bhatia N, Murphy M, Lucente V et al: A comparison of short-term sexual function outcomes for patients undergoing the transvaginal mesh procedure using standard polypropylene mesh vs a hybrid polypropylene/poliglecaprone mesh. (ABSTRACT ONLY).

Blandon RE, Gebhart JB et al. Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Feb 10.

Bobyn JD, Wilson GJ MacGregor DC et al: Effect of pore size on the peel strength of attachment of fibrous tissue to porous surface implants. J. Biomed Mater Res, pp 571-584.

Bohrer JC, Chen CC. Pudendal neuropathy involving the perforating cutaneous nerve after cystocele repair with graft. Obstet Gynecol. 2008 Aug; 112 (2 Pt 2):496-8.

Bontje et al., Follow-up of mesh complication using the IUGA/ICS category-time-site coding classifications. Int Urogynecol J 2014 25:817-822.

Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007) 262-267.

Boukerrou M, Rubod C, Dedet B et al: Tissue resistance of free tension procedure: What about healing? *Int Urogynecol J* (2008) 19:397-400. Published online Sept 2007.

Boulanger L, Boukerrou M, Lambaudie E, Cosson M: Tissue integration and tolerance to meshes used gynecological surgery: an experimental study. *Eur J Obstet Gynecol Reprod Biol.* 2006 Mar 1;125(1):103-8. Epub 2005 Sep 19.

Boulanger L, Moukerrou M et al. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. *Int Urogynecol J* (2008) 19:827-831.

Boulanger L, Boukerrou M, Rubod C et al: Development of an animal model to study meshes used in genital prolapse surgery.

Boyles SH, McCrery R., Dyspareunia and mesh erosion after mesh placement with a kit procedure. *Obstet Gynecol.* 2008 Apr;111(4):969-75.

Bump RC, Mattiasson A, B K, Brubaker LP et al: The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol.* 1996 Jul; 175(1):10- 7.

Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. *Minerva Chir.* 1997 Oct;52(10):1169-76.

Caquant F, Collinet P, Deobodianance P, et al. Safety of transvaginal mesh procedure: Retrospective study of 684 patients. *J Obstet Gynaecol Res.* 2008 Aug;34(4):449-56.

Carey M, Slack M, Higgs P et al: Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device. *BJOG.* 2008 February; 115(3): 391-397.

Carey M, Higgs P. Vaginal repair with mesh vs colporrhaphy for prolapse a randomized controlled trial. *BJOG.* 2009 Sep;116(10):1380-6.

Chmielewski L, Walters MD, Weber AM, et al. Reanalysis of a randomized trial *J Obstet Gynecol* 2011;205:69.el-8.

Chen C, Gustilo-Ashby AM et al. Anatomic relationships of the tension free vaginal mesh trocars. *Am J Obstet Gynecol.* 2007 Dec;197(6):666.el-6.

Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. *Int Urogynecol J.* 2010 Mar;21(3):261-70.

Cobb W, Bums J, Peindl R et al: Textile analysis of heavy weight, mid-weight, and light weight polypropylene mesh in a porcine ventral hernia model. *J Surgical Research* 136, 1-7 (2006).

Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. *Int Urogynecol J* (2006) 17:315-320.

Cosson M, Caquant F et al. Prolift for Pelvic organ prolapse surgical treatment using the TVM group technique - a retrospective study of 687 patients. (ABSTRACT)

Cosson M, Caquant Fetal. Prolift Mesh for pelvic organ prolapse surgical treatment using the TVM group technique - a retrospective study of 96 women under 50. (ABSTRACT)

Cosson M, Rosenthal C, Debodinance P: Prospective clinical assessment for Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse - 3 year results.(ABSTRACT ONLY)

Cosson M, Debodinance P, Boukerrou M et al: Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J (2003) 14: 169-178.

Costello C, Bachman M, Grand, S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007 Sep; 14(3): 168-76.

Culligan PJ, Murphy M, et al. Long term success of abdominal sacral colpopexy using synthetic mesh. Am J Obstet Gynecol. 2002 Dec; 187(6): 1473-80; discussion 1481-2.

Dati et al., Prolift vs. Avaulta for transvaginal repair of severe pelvic prolapse. Int Urogynecol J 2008; 19(Suppl 2):S167-S327 (S248).

Davila G, Baessler K, Cosson M et al: Selection of patients in whom vaginal graft use may be appropriate. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. Int Urogynecol J. 2012 Apr;23 Suppl 1:S7-14. Epub 2012 Mar 7.

De Landsheere L, Ismail S, Lucot JP, Deken V, Foidart JM, Cosson M.: Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7. Epub 2011 Jul 30.

De Tayrac R, Gervaise A, Chauveaud A et al: Combined genital prolapse repair reinforced with a polypropylene mesh and tension-free vaginal tape in women with genital prolapse and stress urinary incontinence: a retrospective case-control study with short-term follow-up. Acta Obstet Gynecol Scand. 2004 Oct;83(10):950-4.

De Tayrac R, Gervaise A, Chauveaud j A et al: Tension-free polypropylene mesh for vaginal repair of anterior vaginal wall prolapse. J Reprod Med. 2005 Feb;50(2):75-80.

De Tayrac R, Deffieux X, Gervaise A et al: Long term anatomical and functional assessment of trans vaginal cystocele repair using polypropylene mesh. Int Urogynecol J Pelvic Floor Dysfunct. 2006 Sep; 17(5):483-8.

De Tayrac R, Picone O, et al. A 2-year anatomical and functional assessment of trans vaginal rectocele repair using a polypropylene mesh. Int Urogynecol J (2006) 17: 100-105.

De Tayrac R, Letouzey V. Basic Science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. *Int Urogynecol J.* 2011 Jul;22(7):775-80.

Debodinance P, Berrocal J, Clave H: Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh. *J Gynecol Obstet Biol Reprod (Paris).* 2004 Nov;33(7):577-88. (original manuscript in French only. Only have English abstract.)

Debodinance P, Engrand J. Development of better tolerated prosthetic materials: applications in gynecological surgery. *J Gynecol Obstet Biol Reprod (Paris).* 2002 Oct;31(6):527-40.

Debodinance P, Cosson M, Collinet P et al: Synthetic meshes for transvaginal surgical cure of genital prolapse: evaluation in 2005. *J Gynecol Obstet Biol Reprod (Paris).* 2006 Sep;35(5 Pt 1):429-54.

Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jan; 18(1):73-9.

Deffieux X, Huel C, De Tayrac R et al: Vaginal mesh extrusion after transvaginal repair of cystocele using a prosthetic mesh: Treatment and functional outcomes. *J Gynecol Obstet Biol Reprod (Paris).* 2006 Nov;35(7):678-84.

Deprest J, Zheng F, Konstantinovic M et al (2006) The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. *Int Urogynecol J* 17:S16-S25.

Dietz H, Vancaillie P, Svehla M. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J Pelvic Floor Dysfunct.* 2003 Oct;14(4):239-43.

Digesu G, Chaliha C, Salvatore S et al: The relationship of vaginal prolapse severity to symptoms and quality of life. *BJOG July 2005 vol. 112:971-976.*

Dindo D, Demartines N, Clavien P: Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg.* 2004 Aug;240(2):205-13.

Diwadkar G, Barber M, Feiner B, et al. Complications and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. *Obstet Gynecol.* 2009 Feb;113(2 Pt 1):367-73.

Ek M, Altman D, Falconer C et al: Effects of anterior trocar guided-transvaginal mesh surgery on lower urinary tract symptoms. *Neurourol Urodyn.* 2010 Nov;29(8):1419-23.

Ek M, Tegeerstedt G, Falconer C et al: Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh. *Neurourol Urodyn.* 2010 Apr;29(4):527-31.

Elmer C, Falconer C, Hallin A et al: Risk factors for mesh complications after trocar guided transvaginal mesh kit repair of anterior vaginal wall prolapse. *Neurourol Urodyn.* 2012 Apr 19. doi: 10.1002/nau.22231.

Elmer C, Blomgren B, Falconer C et al: Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. *J Urol.* 2009 Mar;181(3):1189-95.

Elmer C Altman D, Engh M et al: Trocar-guided transvaginal mesh repair of pelvic organ prolapse. *Obstet Gynecol.* 2009 Jan; 113(1): 117-26.

Falagas M, Velakoulis S, Iavazzo C, et al. Mesh-related infections after pelvic organ prolapse repair surgery. *Eur J Obstet Gynecol Reprod Biol.* 2007 Oct; 134(2): 147-56.

Farrell S, Dempsey T, Geldenhuys L: Histological examination of "fascia" used in colporrhaphy. *Obstet Gynecol.* 2001 Nov;98(5 Pt 1):794-8.

Fatton et al., Sexual outcome after transvaginal repair of pelvic organ prolapse (POP) with or without mesh: a prospective study of 323 patients. *Int Urogynecol J* 2010; 21(Suppl 1):S1-S428 (S79).

Fatton R, Amblard P, Debodinance P. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)--a case series multicentric study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jul; 18(7):743-52.

Feiner et al., A prospective comparison of two commercial mesh kits in the management of anterior vaginal prolapse. *Int Urogynecol J* 2012; 23:279-283.

Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol.* 2010 Feb; 15(2 Pt 1):325-30.

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence.
<http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm>

The Federal and Drug Administration. Urogynecological surgical mesh: Update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse. July 2011.
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>

Firoozi F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. *Urology.* 2010 Jan;75(1):203-6.

Foon R, Tooze-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Dec; 19(12): 1697-706.

Fayyad et al., Prospective study of anterior transobturator mesh kit (Prolift) for the management of recurrent anterior vaginal wall prolapse. *Int Urogynecol J* 2011; 22:157-163.

Gabriel et al., Prolapse surgery in women of 80 years and older using the Prolift technique. *Int Urogynecol J* 2010; 21:1463-1470.

Galleguillos et al., Anterior Prolift like (PL) surgery: Can provoke pelvic organ prolapse (POP) in unaffected posterior compartment. *Int Urogynecol J* 201; 22(Suppl 2):S197-S1768(S890).

Gangam N, Kanee A: Retroperitoneal hemorrhage after a vaginal mesh prolapse procedure. *Obstet Gynecol.* 2007 Aug; 110(2 Pt 2):463-4.

Ganj F, Ibeau O, Bedestani A et al: Complication of transvaginal monofilament polypropylene mesh in POP repair. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009 Aug;20(8):919-25. Epub 2009 Apr 7.

Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery* Vol 193, Issue 4, April 2007, p538-542.

Gauruder-Burmester A, Koutouzidou P et al: Effect of vaginal polypropylene mesh implant on sexual function. *Eur J Obstet Gynecol Reprod Biol.* 2009 Jan;142(1):76-80.

Gutman et al., Three year outcomes of vaginal mesh for Prolapse. *Obstetrics and Gynecology* 2013; 122(4):770-777.

Halaska et al., A randomized multicentric prospective comparison of Prolene meshes and sacrospinous fixation in the treatment of pelvic organ prolapse. *Int Urogynecol J* 2010; ICS abstract 284.

Hamilton B, McCrery R: Dyspareunia and mesh erosion after vaginal mesh placement with a kit procedure. *Obstet Gynecol* 2008, 4:969-975.

Han et al., One year outcome of Gynecare Prolift pelvic floor repair system in the surgical management of pelvic organ prolapse. *Int Urogynecol J* 2008; 19(Suppl 2):S167-S327 (S291).

Hilger W, Walter A, Zobitz M et al: Histological and biomechanical evaluation of implanted graft materials in a rabbit vaginal and abdominal model. *Am J Obstet Gynecol* 2006; 195:1826-31.

Hinoul P, Ombelet W, Matthe P et al: A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh kit (Prolift Anterior) for symptomatic cystocele repair. *J Minim Invasive Gynecol* 2008;15(5):615-620.

Hiltunen R, Takala, T, Heiskanen E et al: Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. *Obstet Gynecol.* 2007 Aug; 110(2 Pt 2):455-62.

Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3-15.

Huang et al., Medium-term comparison of uterus preservation versus hysterectomy in pelvic organ prolapse treatment with Prolift mesh. *Int Urogynecol J* 2015; 26: 1013-1020.

Huffaker et al., A serious complication following placement of posterior Prolift. *Int Urogynecology J* 2009; 20:1383-1385.

Hurtado et al., Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience. *Int Urogynecol J* 2009; 20:11-17.

Iglesia C, Sokol A, Sokol E, et al. Vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol*. 2010 Aug;16(2 Pt 1):293-303.

Ignjatovic I, Stosic D: Retrovesical hematoma after anterior Prolift procedure for cystocele correction. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007 Dec;18(12):1495-7. Epub 2007 Jun 29.

Jacquetin B, Cosson M, Luente V et al: Prospective clinical assessment of the transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse-one year results of 175 patients. (Abstract #291: Presentation International Continence Society 2006).

Jacquetin B, Cosson M: Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009 Aug;20(8):893-6.

Jacquetin B, Patton B, Rosenthal C et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. *Int Urogynecol J*. 2010 Dec;21(12):1455-62.

Jacquetin B, Caquant F, Collinet P: Prolene Soft Mesh for POP surgical treatment - a prospective study of 264 patients. (ABSTRACT ONLY)

Jeffery S, Nieuwoudt A: Beyond the complications: medium-term anatomical, sexual and functional outcomes following removal of trocar-guided transvaginal mesh a retrospective cohort study. *Int Urogynecol J*. 2012 Apr 20. Epub ahead of print.

Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. *BJOG* 2008 Oct; 115(11):1350-61.

Kasturi S, Diaz S, McDermott C et al: De novo stress urinary incontinence after negative prolapse reduction stress testing for total vaginal mesh procedures: incidence and risk factors. *Am J Obstet Gynecol*. 2011 Nov;205(5):487.e1-4. EPub 2011 Jul 20.

Kaufman et al., Age and sexual activity are risk facts for mesh exposure following transvaginal mesh repair. *Int Urogynecol J* 2011; 22:307-313.

Khandwala S, Jayachandran C: Transvaginal mesh surgery for pelvic organ prolapse- Prolift + M: a prospective clinical trial. *Int Urogynecol J*. 2011 Nov;22(11): 1405-11.

Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. *Eur J Surg*. 1999 Jul;165(7):665-73.

Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. *J. Surgical Research* 103, 208-214 (2002).

Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. *European Journal of Surgery Volume 164, Issue 12, pages 965-969, December 1998*

Klinge U, Klosterhalfen M: Modified classification of surgical imeshes for hernia repair based on the analysis of 1,000 explanted meshes. *Hernia*. 2012 Jun;16(3):251-8. Epub 2012

May 5.

Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. *Biomaterials*. 1998 Dec; 19(24):2235-46.

Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] *Chirurg* 2000;71:43-51.

Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. *Expert Rev Med Devices*. 2005 Jan;2(1): 103-17.

Krambeck A, Dora C, Elliott D. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. *Urology*. 2006 May;67(5):1105-10.

Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. *Aust NZ J Obstet Gynaecol*. 2006 Feb;46(1):42-5.

Krause H, Bennett M, Forwood M. Biomechanical properties of raw meshes used in pelvic floor reconstruction. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Dec; 19(12): 1677-81.

Krlin R, Murphy A, Goldman H: Pro: the contemporary use of transvaginal mesh in surgery for pelvic organ prolapse. *Curr Opin Urol*. 2012 May 19. [Epub ahead of print]

Landsheere L, Ismail S, Lucot J et al: Surgical intervention after transvaginal Pro lift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. *Am J Obstet Gynecol*. 2012 Jan;206(1):83.el-7.

LaSala C, Schimpf M: Occurrence of Postoperative hematomas after prolapse repair using a mesh augmentation system. *Obstet Gynecol*. 2007 Feb; 109(2 Pt 2):569- 72.

Lawndy S, Withagen M, Kluivers et al: Between hope and fear: patient's expectations prior to pelvic organ prolapse surgery. *Int Urogynecol J* (2011) 22: 1159-1163.

Lee et al., Transvaginal mesh kits – how “serious” are the complications and are they reversible?

Lensen et al., Comparison of two trocar-guided transvaginal mesh systems for repair of pelvic organ prolapse: a retrospective e cohort study. *Int Urogynecol J* 2013; 24:1723-1731.

Letouzey V, Deffieux X, Gervaise A et al: Transvaginal cystocele repair using a tension-free polypropylene mesh: more than 5 years of follow-up. *Eur J Obstet Gynecol Reprod Biol*. 2010 Jul;151(1):101-5.

Liang et al., Sexual function in women following transvaginal mesh procedures for the treatment of pelvic organ prolapse. *Int Urogynecol J* 2012; 23:1455-1460.

Lo et al., Predictors for de novo stress urinary incontinence following extensive pelvic reconstructive surgery. *Int Urogynecol J* 2015; 26:1313-1319.

Long et al., Comparison of clinical outcome and urodynamic findings using Perigee and /or Apogee versus Prolift anterior and/or Posterior system devices for the treatment of pelvic organ prolapse. *Int Urogynecol J* 2011; 22:233-239.

Lopes E, Lemos N, Carramao S et al: Transvaginal polypropylene mesh versus sacrospinous ligament fixation for the treatment of uterine prolapse: 1-year follow-up of a randomized controlled trial. *Int Urogynecol J.* 2010 Apr;21(4):389-94.

Lowder JL, Park AJ, Ellison R et al. The role of apical vaginal support in the appearance of anterior and posterior vaginal prolapse. *Obstet Gynecol.* 2008 Jan;111(1): 152-7.

Lowman J, Jones L, Woodman P: Does the Prolift System cause dyspareunia? *Am J Obstet Gynecol.* 2008 Dec;199(6):707.el-6.

Lucente V, Hale D, Miller D et al: A clinical assessment of Gynemesh PS for the repair of pelvic organ prolapse (POP). (POSTER PRESENTATION ONLY)

Lucente V, Milani A, VanDrie D et al: A lightweight mesh for transvaginal mesh repair- interim 3 month results. (ABSTRACT ONLY)

Lucente V, Molden, S, Barker, M, Karram, M, Point-Counterpoint: Transvaginal Placement of Synthetic Grafts to repair Pelvic Organ Prolapse, Current Bladder Dysfunction Reports, 2008.

Lucente V, Jacquetin B, Miller D, et al: Tranvaginal Mesh (TVM) An innovative approach to placing synthetic mesh transvaginally for surgical correction of pelvic support defects--perioperative safety results. (ABSTRACT AND VIDEO SUBMISSION ONLY)

Lucente V, Miller D, Babin B: Prospective clinical assessment of the Total Vaginal Mesh (TVM) technique for treatment of pelvic organ prolapse (POP) 6 &12 month results. (ABSTRACT ONLY)

Luciani A, Rapp D, Gong E et al: The surgical technique and early postoperative complications of the Gynecare Prolift pelvic floor repair system. *Can J Urol.* 2008 Apr; 15(2):4004-8.

Lukban et al., Single-incision apical and posterior mesh repair: 1-year prospective outcomes. *Int Urogynecol J* 2012; 23:1413-1419.

Maher C, Feiner B, Baessier K, et al. Surgical management of pelvic organ prolapse in women. The updated summary version Cochrane review. *Int Urogynecol J.* 2011 Nov;22(11):1445-57. Epub 2011 Sep 17.

Mamy L, Letouzey V, Lavigne J, et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J.* 2011 Jan;22(1): 47-52.

Marchionni M, Bracco G, Checcucci V: True incidence of vaginal vault prolapse. Thirteen years of experience. *J Reprod Med.* 1999 Aug;44(8):679-84.

Margulies R, Lewicky C, Dee Fetal: Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol* 2008; 199:678.el-678.e4.

Martan A, Svabik K, et al. Incidence and prevalence of complications after urogynecological and reconstructive pelvic floor surgery. Ceska Gynekol. 2007 Dec;72(6):410-5.

Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. BJOG. 2005 Jan;112(1):107-11.

Milani A, Withagen M, Vierhout M: Trocar-guided total tension-free vaginal mesh repair of post-hysterectomy vaginal vault prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Oct;20(10):1203-11.

Milani A, Hinoul P, Gauld J, Casson M, Prolift+M Investigators: Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcome. Am J Obstet Gynecol. 2011 Jan;204(1):74.e1-8. Epub 2010 Oct 20.

Milani R, Withagen M, The H et al: Sexual function following trocar-guided mesh or vaginal native tissue repair in recurrent prolapse: a randomized controlled trial. J Sex Med. 2011 Oct;8(10):2944-53.

Miller D, Lucente V, Babin E et al: Prospective clinical assessment of the transvaginal meshtchnique treatment of pelvic organ prolapse - 5-year results. Female Pelvic Med Reconstr Surg. 2011 May; 17(3): 139-43.

Mokrzycki M, Hampton B: Pelvic arterial embolization in the setting of acute hemorrhage as a results of the anterior Prolift Procedure. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Jul;18(7):813-5.

Murphy M, Sternschuss G, Haff R, van Raalte H, Lucente V: Quality of life and surgical satisfaction after vaginal reconstructive vs. obliterative surgery for the treatment of advanced pelvic organ prolapse. Am J Obstet Gynecol. 2008 May;198(5):573.e1-7.

Murphy (Lucente, Goldman) - Time to rethink: an evidence-based response from pelvic surgeons to the FDA safety communication: "Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse." Int Urogynecol J (2012) 23:5-9.

Natale, F, La Penna C, Padoa A et al: A prospective randomized controlled study comparing Gynemeshfi, a synthetic mesh, and Pelvicolfi, a biologic graft, in the surgical treatment of recurrent cystocele. Int Urogynecol J (2009) 20:75-81.

Nieminen K, Hiltunen R, Takala T, et al. Outcomes after anterior wall repair with mesh: a randomized controlled trial with a 3 year follow-up. Am J Obstet Gynecol. 2010 Sep;203(3):235.

Nieminen K, Hiltunen R, Heiskanen E et al: Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec;19(12):1611-6.

Nyguyen J, Burchette R. Outcomes after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol. 2008; 111(4):891-8.

Olsen A, Smith V, Bergstrom J: Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol. 1997 Apr;89(4):501-6.

Ostergard D: Polypropylene vaginal mesh grafts in gynecology. *Obstet Gynecol.* 2010 Oct; 116(4):962-6.

Ozog et al., Biomechanical effect of polyglencaprone fibers in a polypropylene mesh after abdominal and rectovaginal implantation in a rabbit *Int Urogynecol J* 2012; 23:1397-1402.

Pacquee S, Palit G, Jacquemyn Y: Complications and patient satisfaction after transobturator anterior and/or posterior tension-free vaginal polypropylene mesh for pelvic organ prolapse. *Acta Obstet Gynecol Scand.* 2008;87(9):972-4.

Pandit A, Henry J. Design of surgical meshes - an engineering perspective. *Technol Health Care.* 2004;12(1):51-65.

Patel et al., Transvaginal mesh for pelvic organ prolapse: 10-year experience with 627 procedures. *Int Urogynecol J* 2012; 23 Suppl 2: S43-244 (S203).

Paplamata E, Balaxix D, Pantelis T et al: Genital floor repair using polypropylene meshes: a comparative study. (ABSTRACT ONLY)

Pizarro et al., Risk factors for mesh shrinkage and erosion in Prolift like (PL) surgery: can menopausal status and dyslipidemia explain them? *Int Urogynecol J* 2010; 21 (Suppl 1):S1-S428 (161).

Price et al., Vaginal Prolapse surgery with synthetic mesh augmentation in the UK: analysis of the British Society of Urogynecologists' (BSUG) database. In *Urogynecol J* 2011; 22 (Suppl 2):S197-S1768(S847)

Roy S, Mohandas A, Coyne K et al: Assessment of the psychometric properties of the short-form prolapse/urinary incontinence sexual questionnaire (PISQ-12) following surgical placement of Prolift+M: A transvaginal partially absorbable mesh system for the treatment of pelvic organ prolapse. *J Sec Med* 2012;9: 1190-1199.

Tunn R, Picot A, Marschke J, et al: Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. *Ultrasound Obstet Gynecol* 2007; 29:449-452.

Pierce L, Grunlan M, Hou Y et al: Biomechanical properties of synthetic and biologic graft material following long-term implantation in the rabbit abdomen and vagina. *Am J Obstet Gynecol.* 2009 May;200(5):549.e1-8.

Pubill et al., Complications and patient satisfaction after transvaginal repair of genital prolapse using a tension free vaginal mesh (Prolift). *Int Urogynecol J* 2011; 22(Suppl 3):S1769-2008 (S1798).

Reisenauer C, Kirshniak A, Drews U et al: Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. *Eur J Obstet and Gynecol Repr Biol* 2007;131:214-25.

Rogowski et al., Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair. *Int Urogynecol J* 2013;24:2087-2092.

Rogowski et al., Retrospective comparison between the Prolift and Elevate anterior vaginal mesh procedures: 18-month clinical outcome. *Int Urogynecol J* published online July 4, 2015.

Rosch R, Junge K, Holzl Fetal (2004) How to construct a mesh. In: Schumpelick V, Nyhus LM (eds) *Meshes: benefits and risks*. Springer, Berlin, pp 179-184.

Rosengren A, Bjursten L., Pore size in implanted polypropylene filters is critical for tissue organization. *J Biomed Mater Res A*. 2003 Dec;67(3):918-26.

Rubod C, Boukerrou M, Brieu M et al: Biomechanical properties of vaginal tissue: preliminary results. *Int Urogynecol J* (2008) 19:811-816.

Seker D, Kulacoglu H. Long-term complications of mesh repairs for abdominal wall hernias. *J Long Term Eff Med Implants*. 2011;21(3):205-18.

Shek D, Dietz H, Rane A et al: Transobturator mesh for cystocele repair. a short to medium term follow up using 3D/4D ultrasound. *Ultrasound Obstet Gynecol*. 2008; 32:82-86.

Sikirica et al., Treatment outcomes of the Gynecare Prolift pelvic floor repair system: a systematic literature review. *Int Urogynecol J* 2009; 20(Suppl 3):S241-S491(S260).

Simon M, Debodinance P: Vaginal prolapse repair using the Prolift Kit: a registry of 100 successive cases. *Eur J Obstet Gynecol Reprod Biol*. 2011 Sep;158(1):104-9.

Sivaslioglu A, Unlubilgin E, Dolen I. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocele. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Apr;19(4):467-71.

Song Y, Ye P, Hong X et al: Changes in levator ani muscle after vaginal hysterectomy and prolapse repair using total Prolift. *Int J Gynaecol Obstet*. 2009 Jul;106(1):53-6. Epub 2009 Apr 8.

Srikrishna S, Robinson D, Cardozo L: A longitudinal study of patient and surgeon goal achievement 2 years after surgery following pelvic floor dysfunction surgery. *BJOG*. 2010 Nov;117(12):1504-11.

Srikrishna S, Robinson D, Cardozo L, et al: Experiences and expectation of women with Urogenital prolapse: a quantitative and qualitative exploration. 2008. *BJOG* 115:1362-1368

Su T, Lau H, Huang W et al: Short term impact on female sexual function of pelvic floor reconstruction with the Prolift procedure. *J Sex Med*. 2009 Nov;6(11):3201-7.

Svabik et al., Vaginal mesh shrinking – ultrasound assessment and quantification. *Int Urogynecol J* 2009; 20 (Suppl 2): S73-S239(S166).

Takeyama M, Koyama M, Murakami Get al: Nerve preservation in the tension free vaginal mesh procedures for pelvic organ prolapse - a cadaveric study. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Apr;19(4):559-66. Epub 2007 Oct 10.

Tamussino K, Hanzal E, Kolle D et al: Tension-free vaginal tape operation: results of the Austrian Registry. *Obstet Gynecol.* 2001 Nov;98(5 Pt 1):732-6.

Tijdink M, Vierhout M, Heesakker J, et al: Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. *Int Urogynecol J* 2011 Nov;22(11):1395-404.

Timmer M: Technical note - Evaluation of Mesh contraction in a swine fascia Implantation Model. (ABSTRACT ONLY)

Touboul - Major Venous Hemorrhagic Complication during Transvaginal cystocele repair using the transobturator approach.

Touboul et al., Perineal approach to vascular anatomy during transobturator cystocele repair. *BJOG* 2009;1169:708-712.

U.S. Preventive Services Task Force (August 1989). Guide to clinical preventive services: report of the U.S. Preventive Services Task Force. DIANE Publishing. pp. 24-. ISBN 978-1-56806-297-6.

Vaiyapuri G, Han H, Lee L et al: Use of the Gynecare Prolift System in surgery for pelvic organ prolapse: 1-year outcome. *Int Urogynecol J.* 2011 Jul;22(7):869-77.

Vakili B, Trang H, Loesch H et al: Outcomes of vaginal reconstructive surgery with and without graft material. *American Journal of Obstetrics and Gynecology* (2005) 193:2126-32.

Van Raalte H, Lucente V, Molden S, et al: One-year anatomic and quality-of-life outcomes after the Prolift procedure for treatment of post-hysterectomy prolapse. *Am J Obstet Gynecol.* 2008 Dec;199(6):694.e1-6.

Velemir L, Amblard J, Patton B et al: Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. *Ultrasound Obstet Gynecol.* 2010 Apr;35(4):474-80.

Vierhout M, Withagen M, Putterer J: Rectal obstruction after a vaginal posterior compartment polypropylene mesh fixed to the sacrospinous ligaments. *Int Urogynecol J* (2011) 22:1035-1037.

Voskerician et al., Evaluation of local tolerance of lightweight meshes in animal model. *Int Urogynecol J* 2010; 21(Suppl 1):S400.

Walid MS, Heaton RL: Laparoscopic apical mesh excision for deep dyspareunia caused by mesh banding in the vaginal apex. *Arch Gynecol Obstet.* 2009 Sep;280(3):347-50.

Wall L, Brown D: The perils of commercially driven surgical innovations. *Am J Obstet Gynecol.* 2010 Jan;202(1):30.e1-4. Epub 2009 Jul 15.

Weber AM, Abrams P, Brubaker L., The Standardization of terminology for researchers in female pelvic floor disorders. *Int Urogynecol J* (2001)12: 178-186.

Weber AM, Walters MD, Piedmonte MR, et al: Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001 Dec;185(6):1299-304; discussion 1304-6.

Wetta LA, Gerten K, Wheeler T et al: Synthetic Graft Use in Vaginal Prolapse Surgery: Objective and Subjective Outcomes. Int Urogynecol J Pelvic Floor Dysfunct. 2009 November; 20(11): 1307-1312. doi: 10.007/s00192-009-0953-3.

Withagen et al., High effectiveness and satisfaction one year after tension free vaginal mesh (Prolift) surgery. Int Urogynecol J 2008; 19(Suppl 1):S111.

Withagen et al., Tension free vaginal mesh compared to conventional vaginal prolapse surgery in recurrent prolapse; a randomized controlled trial. Int Urogynecol J 2009; 20 (Suppl 2):S73-S239.

Withagen et al., Does trocar-guided tension-free vaginal mesh (Prolift) repair provoke prolapse of the unaffected compartments. Int Urogynecol J 2010;21:271-278.

Withagen M, Milani A, den Boon J, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol. 2011 Feb;117(2 Pt 1):242-50.

Withagen M, Vierhout M, Hendricks J, et al: Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedures. Obstet Gynecol. 2011 Sep;118(3):629-36.

Zyczynski H, Carey M, Robinson D, Sikirica V, et al: One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. (ABSTRACT ONLY presentation American Urological Association, 2009 and International Urogynecological Association meeting 2009).

ETHICON CORPORATE DOCUMENTS

ETH-00002.
ETH-00005.
ETH-00006.
ETH-00252 Gynemesh Patient Brochure.
ETH-00256.
ETH-00260.
ETH-00293.
ETH-00929-0030.
ETH-00943.
ETH-00986 Device Descriptions Similarities.
ETH-01032.
ETH-01039.
ETH-01074-01235.
ETH-0118.
ETH-01120.
ETH-01121.
ETH-01242 Dec 20 2007 letter to Ethicon.
ETH-01292.
ETH-01322.
ETH-01761-01769.
ETH-01762.
ETH-01764.
ETH-01777.
ETH-02325.

ETH-02601.
ETH-02683-02696.
ETH-03231.
ETH-03560.
ETH-07156.
ETH-00011724.
ETH-17369.
ETH-17621.
ETH-18906.
ETH-18935
ETH-47351.
ETH-47352.
ETH-47353.
ETH-48281.
ETH-48769.
ETH-51072.
ETH-51573.
ETH-51575.
ETH-53061.
ETH-60103.
ETH-60136.
ETH-60137.
ETH-60142.
ETH-60173.
ETH-60554.
ETH-71304.
ETH-71307.
ETH-77061.
ETH-80249.
ETH-80265.
ETH-80270.
ETH-80271-08272.
ETH-80297.
ETH-80303.
ETH-80308.
ETH-80318.
ETH-80636-80644.
ETH-80643 Complications.
ETH-80645-80651.
ETH-80656.
ETH-82320.
ETH-82419.
ETH-87999.
ETH-00005.
ETH-00386.
eth.mesh.00035379.
ETH-00253.
ETH-00255-000258 Ethicon Marketing Brochure.
ETH-00264.
ETH-00382.
ETH-00383.
ETH-00384.
ETH-00385.
ETH-00797-00927.
ETH-00933-00934.
ETH-01321.
ETH-01363-01365.
ETH-01624.
ETH-01643.
ETH-01671 Prolift IFU .

ETH-02707-02708.	
ETH-02709.	
ETH-02711.	
ETH-02713.	
ETH-02794.	
ETH-02813.	
ETH-03260-03271	Prolift Product Description Document.
ETH-03272-03419	Prolift Design Requirements Matrix.
ETH-03281.	
ETH-03420-03479	Prolift design & development.
ETH-03430.	
ETH-03480-03530	Concept DDSA.
ETH-03531-03567	Final DDSA.
ETH-03568-03578	Design failure modes effects analysis.
ETH-03579-03876	Development Completion Report.
ETH-03611.	
ETH-03650.	
ETH-03672.	
ETH-03747.	
ETH-03767.	
ETH-04022-04068	Material Specifications.
ETH-04069-04355	test methods.
ETH-04240-03479	Prolift Design & Development Plan overview, design input, history,
biocompatibility.	
ETH-04356-04714	Test methods validation.
ETH-04715-05138	Test methods validation.
ETH-05139-05143	Supplier Status.
ETH-05144-05145	Process map.
ETH-05146-05199	Operational equipment summary.
ETH-05200-05503	Operational equipment summary.
ETH-06019-06025	Finished good specifications.
ETH-06026-06029	Process specifications.
ETH-06229-06256	Content of surgical technique document and IFU.
ETH-06635-06641	Guide documents.
ETH-07152-07158	Clinical expert report.
ETH-07304-07310.	
ETH-07427-07433.	
ETH-07434-07494.	
ETH-07495-07545.	
ETH-07546-07609.	
ETH-07712	Ethicon advertisement.
ETH-08028.	
ETH-16986	IFU Statement.
ETH-17061	IFU Statement.
ETH-19622.	
ETH-19645.	
ETH-19943	Hydrodissection description.
ETH-19944.	
ETH-19945.	
ETH-48130.	
ETH-49659.	
ETH-60102.	
ETH-60136.	
ETH-60142.	
ETH-60149.	
ETH-60151.	
ETH-62214.	
ETH-62799.	
ETH-62803	Revised IFU.
ETH-65876	Original Prolift IFU.

ETH-70371.
ETH-70373.
ETH-74435.
ETH-76140.
ETH-76182.
ETH-76690.
ETH-076774.
ETH-80289.
ETH-80640.
ETH-80641.
ETH-80643 Complications.
ETH-80657.
ETH-80660.
ETH-83193.
ETH-83318.
ETH-83323.
ETH-83452.
ETH-83788.
ETH-85678 Email from Butrick to Robinson.
ETH-00386.
ETHMESH00419571-00419600 Prolift Technique.
ETHMESH00419572.
ETHMESH00419573.
ETHMESH00419575.
ETHMESH00419576.
ETHMESH00419578.
ETHMESH00419579.
ETHMESH00419582.
ETHMESH00419584.
ETHMESH00419585.
ETHMESH00067356-00067363 Lucente Webinar Transcription.
EWHU website.
01-27-09 Email from Maroulis Jones pdf.
ETH-18951 pdf.
ETH-18953 pdf.
ETH-18963 Meeks pdf.
ETH-18967-18975 pdf.
ETH-60136-60137 pdf.
ETH-60136 pdf.
ETHMESH00008039 pdf.
Ethmesh00008041-00008042 pdf.
Ethmesh00008043-00008112 pdf.
Ethmesh00126954 pdf.
ETHMESH02010835.
ETHMESH00869977.
ETHMESH02589032-ETHMESH 02589079.
ETHMESH00126954.
1/27/09 email from Maroulis to Jones.
ETH-60136-60137.
ETHMESH00008043-00008112.
ETH-18967-18975.
ETHMESH00008039-00008040.
ETH-18953-18954.
ETH-18951-18952.
ETH-18963.
ETH MESH00008041-00008042.
ETH-18761-18763.
ETH-83454-83455.
ETH MESH00000272.

ETH-80645-80651.

ETH-76139.

ETH-76140-76145.

ETH MESH00011731-00011736.

ETH-01383-01398.

ETH-00940-00944.

ETH MESH.00126755 – 00126757.

May 15, 2000 letter from FDA to Ethicon.

510 (k) Application.

ETH MESH00062770-00062789 (Clinical Data Synopsis: Prolift).

ETH MESH00870466-0080475 Expert meeting with Klasterhalfen 2006.

ETH MESH02010834-0201855 Biomechanical consideration for pelvic floor mesh design.

ETH MESH03719177-03719195.

Vailhe focus on exposure Road to Improvement 10-14-11.

ETH MESH00570955-00570956 Prolapse mesh explants 6-2009.

ETH MESH02017152-02017158 2-23-07 Expert Meeting.

ETH MESH00006636 Klosterhalfen Interim report mesh explants pelvic floor.

ETH MESH02589032-02589079 PA Consulting Group Investigating Mesh erosion in pelvic floor.

ETH MESH00869977-00870098 Peter A Meier (Principal Scientist J&J) Clinical evaluation report on mesh review.

ETH-18906-18920 (Study abstracts).

ETH-00986-00990 (Device Descriptions and Similarities).

ETH-18935-18950 (Design Validation Protocol).

ETH-00252-00265 (Marketing materials).

Regional Meeting documents.

ETH-18976-19660 (Pelvic Organ Prolapse Surgery, a presentation by David B. Robinson, MD).

ETH MESH02341454-459 ETH.MESH.00870466.

ETH MESH01782867 ETH-77061.

ETH MESH00081478.

ETH MESH00329334: June 30, 2006 email from Meng Chen to Mark Yale re: The Feedback from the Medical Directors for the IFU updates.

ETH MESH00329335-36.

ETH-80643.

ETH MESH PM. 000019 ETH-01242.

ETH-01761 .

ETH-48769.

ETH-80318.

ETH-80645-80651.

ETH-80249.

ETH-01762.

ETH-80297.

ETH-80646.

ETH-65877-65884.

ETHMESH03905968

ETHMESH00095913

ETHMESH03905968

ETHMESH0329334

ETHMESH0329335

ETHMESH00329334

ETHMESH00329335-36

NEW IFU.

Original IFU.

Prolift Clinical Data Synopsis.
Southern Midwest Regional Meeting
06/07/08 email from St. Hilaire to Maher & Jones
Parisi Testimony re: changes to IFU's or Prof. ED materials since new warnings/IFU's
Parisi testimony re changes to IFU's or Prof ED Materials since new warnings updates.pdf

DEPOSITIONS

Piet Hinoul, MD, Ph.D

David Robinson, MD

Aaron Kirkemo, MD

Zenobia Walji

Judy Gauld

Scott Ciarrocca

Matthew Henderson

Paul Parisi

Dr. Martin Weisberg

Dr. Axel Arnaud

Dr. Joerg Holste

Jennifer Paine

Catherine Beath

Dr. Aran Maree

Daniel Smith

Sean O'Bryan

Charlotte Owens

Dr. James Hart

Bryan Lisa

Brian Kanerviko

Price St. Hilaire

Alex Gorsky

Renee Selman

Cliff Volpe

DVD's:

ETH.MESH.PM. 000019

ETH.MESH.PM. 000001

ETH.MESH.PM. 000058

ETH.MESH.PM. 000057

ETH.MESH.PM. 000027

ETH.MESH.PM. 000007

ETH.MESH.PM. 000011

ETH.MESH.PM. 000032

ETH.MESH.PM. 000052

ETH.MESH.PM. 000039

ETH.MESH.PM. 000037

PLAINTIFFS' MEDICAL RECORDS

PLAINTIFF'S DEPOSITION W/EXHIBITS

PLAINTIFF'S FACT SHEET

TREATING DOCTORS' DEPOSITION W/EXHIBITS:

Dr. Patricia Murray

Dr. Charles Beamon

Dr. Edward Gill

GENERAL EXPERT REPORTS FILED IN THE LITIGATION

TVT RELIANCE LIST

MEDICAL PUBLICATIONS:

Abdel Fattah I, Ramsey I. Retrospective multicentre study of the new minimally invasive mesh repair devices for POP. BJOG. 2008 Jan; 115(1):22-30.

Abdel-Fattah et al., Randomized prospective single blinded study comparing “inside out” versus “outside in” transobturator tapes in the management of urodynamic stress incontinence; 1-year outcomes from the E-TOT study. BJOB 2010; 117:870-8

Abed H, Rahn D, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011 Jul;22(7):789-98.

Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair. Surg laparosc endosc percutan tech 2007, 17:91-94.

Altman D, Falconer C. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. Obstet Gynecol. 2007 Feb; 109(2 Pt 1):303-8.

Altman D, Tappio V et al. Short-term outcome after transvaginal mesh repair of POP. Int Urogynecol J (2008) 19:787-793.

ALTMAN D, Vayrynen T, Engh M: Anterior colporrhaphy versus transvaginal mesh for pelvic organ prolapse. N Engl J Med. 2011 May 12;364(19):1826-36.

Altman D, Elmer C Kiiholma P et al: Sexual dysfunction after trocar-guided transvaginal mesh repair of pelvic organ prolapse. Obstet Gynecol. 2009 Jan;113(1):127-33.

Altman D, Zhang A, Falconer C: Innervation of the rectovaginal wall in patients with rectocele compared to healthy controls. Neurourology and Urodynamics 25:776-781.

Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1: 15-21.

Amrute KV, Eisenberg ER. Analysis of outcomes of single polypropylene mesh in total pelvic floor reconstruction. Neurourology and Urodynamics 26:53-58, 2007. [uses AMS apogee and perigee]

Angioli et al., Tension-free vaginal tape versus transobturator suburethral tape: five-year follow up results of a prospective randomised trial. European Urology 2010; 58:671-7.

Araco et al., 1VT-Ovs. 1VT: a randomized trial in patients with different degrees of urinary stress incontinence. *Int Urogynecol J* 2008; 19:917-926.

Argirovic RB, Gudovic AM et al, Transvaginal repair of genital prolapse with polypropylene mesh using tension-free technique. *Eur J Obstet Gynecol Reprod Biol*. 2010 Nov; 153(1):104-7.

Aungst MJ, Friedman EB. De novo stress incontinence and pelvic symptoms after transvaginal mesh repair. *Am J Obstet Gynecol*. 2009 Jul;201(1):73.e1-7.

Bader G, Fauconnier A, Roger Net al: Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh. Technique and results. *Gynecologie Obstetrique & Fertilite* 32 (2004) 280-284.

Baessler K, Maher C: Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits. *Curr Opin Obstet Gynecol*. 2006 Oct;18(5):560-6.

Bafghi A, Lannelli A, Verger S et al: Transvaginal repair of genital prolapse with Prolift: evaluation of safety and learning curve. *J Gynecol Obstet Biol Reprod (Paris)*. 2009 Feb;38(1):77-82. Epub 2008 Nov 25.

Barber M, Brubaker L, Nygaard, I et al. Defining success after surgery for pelvic organ prolapse. *Obstet Gynecol*. 2009 September; 114(3): 600-609.

Bellon J, Honduvilla N, Jurado Fetal: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. *Biomaterials*. 2001 Jul;22(14):2021-4.

Benhaim Y, de Tayrac R, Deffieux X, Gervaise A et al: Treatment of genital prolapse with a polypropylene mesh inserted via the vaginal route. Anatomic and functional outcome in women aged less than 50 years. *J Gynecol Obstet Biol Reprod (Paris)*. 2006 May;35(3):219-26.

Berrocal J, Clave H, Cosson M (The TVM Group) et al: Conceptual advances in the surgical management of genital prolapse. *J Gynecol Obstet Biol Reprod* 2004; 33:577-587.

Bhandari M, Busse J, Jackowski D et al: Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. *CMAJ*. 2004 Feb 17;170(4):477-80.

Bhatia N, Murphy M, Luente V et al: A comparison of short-term sexual function outcomes for patients undergoing the transvaginal mesh procedure using standard polypropylene mesh vs a hybrid polypropylene/poliglecaprone mesh. (ABSTRACT ONLY).

Bianchi-Ferrero et al., Randomized controlled trial comparing 1VT-O and 1VT-S for the treatment of stress urinary incontinence: 2-year results. *Int Urogynecol J* 2014; 25:1343-1348.

Blandon RE, Gebhart JB et al. Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009 Feb 10.

Bobyn JD, Wilson GJ MacGregor DC et al: Effect of pore size on the peel strength of attachment of fibrous tissue to porous surface implants. *J. Biomed Mater Res*, pp 571-584.

Bohrer JC, Chen CC. Pudendal neuropathy involving the perforating cutaneous nerve after cystocele repair with graft. *Obstet Gynecol.* 2008 Aug; 112 (2 Pt 2):496-8.

Boukerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. *European J. Obstet & Gynecol and Repro Bio* 134: (2007) 262-267.

Boukerrou M, Rubod C, Dedet B et al: Tissue resistance of free tension procedure: What about healing? *Int Urogynecol J* (2008) 19:397-400. Published online Sept 2007.

Boulanger L, Boukerrou M, Lambaudie E, Cosson M: Tissue integration and tolerance to meshes used gynecological surgery: an experimental study. *Eur J Obstet Gynecol Reprod Biol.* 2006 Mar 1;125(1):103-8. Epub 2005 Sep 19.

Boulanger L, Moukerrou M et al. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. *Int Urogynecol J* (2008) 19:827-831.

Boulanger L, Boukerrou M, Rubod C et al: Development of an animal model to study meshes used in genital prolapse surgery.

Boyles SH, McCrery R., Dyspareunia and mesh erosion after mesh placement with a kit procedure. *Obstet Gynecol.* 2008 Apr;111(4):969-75.

Bump RC, Mattiasson A, B K, Brubaker LP et al: The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol.* 1996 Jul; 175(1):10- 7.

But et al., Complications and short-term results of two different transobturator techniques for a surgical treatment of women with urinary incontinence: a randomized study. *Int Urogynecol J* 2008; 19:857-861.

Canelet al., Postoperative groin pain and successrates following transobturator midurethral sling placement: 1VT ABBREVO system versys 1VT-Obturator System.

Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. *Minerva Chir.* 1997 Oct;52(10):1169-76.

Caquant F, Collinet P, Deobodianance P, et al. Safety of transvaginal mesh procedure: Retrospective study of 684 patients. *J Obstet Gynaecol Res.* 2008 Aug;34(4):449-56.

Carey M, Slack M, Higgs P et al: Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device. *BJOG.* 2008 February; 115(3): 391-397.

Carey M, Higgs P. Vaginal repair with mesh vs colporrhaphy for prolapse a randomized controlled trial. *BJOG.* 2009 Sep;116(10):1380-6.

Charalambous et al., Transvaginal vs transobturator approach for synthetic sling placement in patients with stress urinary incontinence. *Int Urogynecol J* 2008; 19:357-360.

Chmielewski L, Walters MD, Weber AM, et al. Reanalysis of a randomized trial *J Obstet Gynecol* 2011;205:69.el-8.

Chen C, Gustilo-Ashby AM et al. Anatomic relationships of the tension free vaginal mesh trocars. Am J Obstet Gynecol. 2007 Dec;197(6):666.e1-6.

Chen et al., Efficacy and postoperative complications of tension-free vaginal tape Secur for female stress urinary incontinence. Chinese Medical Journal 2011; 124(9):1296-1299.

Cheng et al., Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. European Journal of Obstetrics and Gynecology and Reproductive Biology 2012;161:228-231.

Cholhan et al., Dyspareunia associated with paraurethral banding in the transobturator sling. American Journal of Obstetrics and Gynecology 2010;481.e1.

Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70.

Cobb W, Bums J, Peindl R et al: Textile analysis of heavy weight, mid-weight, and light weight polypropylene mesh in a porcine ventral hernia model. J Surgical Research 136, 1-7 (2006).

Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J (2006) 17:315-320.

Cosson M, Caquant F et al. Prolift for Pelvic organ prolapse surgical treatment using the TVM group technique - a retrospective study of 687 patients. (ABSTRACT)

Cosson M, Caquant Fetal. Prolift Mesh for pelvic organ prolapse surgical treatment using the TVM group technique - a retrospective study of 96 women under 50. (ABSTRACT)

Cosson M, Rosenthal C, Debodinance P: Prospective clinical assessment for Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse - 3 year results.(ABSTRACT ONLY)

Cosson M, Debodinance P, Boukerrou M et al: Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J (2003) 14: 169-178.

Costello C, Bachman M, Grand, S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007 Sep; 14(3): 168-76.

Culligan PJ, Murphy M, et al. Long term success of abdominal sacral colpopexy using synthetic mesh. Am J Obstet Gynecol. 2002 Dec; 187(6): 1473-80; discussion 1481-2.

Davila G, Baessler K, Cosson M et al: Selection of patients in whom vaginal graft use may be appropriate. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. Int Urogynecol J. 2012 Apr;23 Suppl 1:S7-14. Epub 2012 Mar 7.

Deffieux et al., Transobturator TTVT-O versus retropubic TTVT: results of a multicenter randomized controlled trial at 24 months follow-up. Int Urogynecol J 2010; 21:1337-1345.

De Landsheere L, Ismail S, Lucot JP, Deken V, Foidart JM, Cosson M.: Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years median follow-up. *Am J Obstet Gynecol.* 2012 Jan;206(1):83.e1-7. Epub 2011 Jul 30.

De Leval et al., The Orginal versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. *Int Urogynecol J* 2011;22:145-56.

De Levbal et al, Modified inside-out transobturator procedure: reply by the authors. *Int Urogynecol J* 2011;22:767

De Tayrac R, Gervaise A, Chauveaud A et al: Combined genital prolapse repair reinforced with a polypropylene mesh and tension-free vaginal tape in women with genital prolapse and stress urinary incontinence: a retrospective case-control study with short-term follow-up. *Acta Obstet Gynecol Scand.* 2004 Oct;83(10):950-4.

De Tayrac R, Gervaise A, Chauveaud A et al: Tension-free polypropylene mesh for vaginal repair of anterior vaginal wall prolapse. *J Reprod Med.* 2005 Feb;50(2):75-80.

De Tayrac R, Deffieux X, Gervaise A et al: Long term anatomical and functional assessment of trans vaginal cystocele repair using polypropylene mesh. *Int Urogynecol J Pelvic Floor Dysfunct.* 2006 Sep; 17(5):483-8.

De Tayrac R, Picone O, et al. A 2-year anatomical and functional assessment of transvaginal rectocele repair using a polypropylene mesh. *Int Urogynecol J* (2006) 17: 100-105.

De Tayrac R, Letouzey V. Basic Science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. *Int Urogynecol J.* 2011 Jul;22(7):775-80.

Debodinance P, Berrocal J, Clave H: Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh. *J Gynecol Obstet Biol Reprod (Paris).* 2004 Nov;33(7):577-88. (original manuscript in French only. Only have English abstract.)

Debodinance P, Engrand J. Development of better tolerated prosthetic materials: applications in gynecological surgery. *J Gynecol Obstet Biol Reprod (Paris).* 2002 Oct;31(6):527-40.

Debodinance P, Cosson M, Collinet P et al: Synthetic meshes for transvaginal surgical cure of genital prolapse: evaluation in 2005. *J Gynecol Obstet Biol Reprod (Paris).* 2006 Sep;35(5 Pt 1):429-54.

Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jan; 18(1):73-9.

Deffieux X, Huel C, De Tayrac R et al: Vaginal mesh extrusion after transvaginal repair of cystocele using a prosthetic mesh: Treatment and functional outcomes. *J Gynecol Obstet Biol Reprod (Paris).* 2006 Nov;35(7):678-84.

Deprest J, Zheng F, Konstantinovic M et al (2006) The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. *Int Urogynecol J* 17:S16-S25.

Dietz H, Vancaillie P, Svehla M. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J Pelvic Floor Dysfunct.* 2003 Oct;14(4):239-43.

Digesu G, Chaliha C, Salvatore S et al: The relationship of vaginal prolapse severity to symptoms and quality of life. *BJOG* July 2005 vol. 112:971-976.

Dindo D, Demartines N, Clavien P: Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg.* 2004 Aug;240(2):205-13.

Diwadkar G, Barber M, Feiner B, et al. Complications and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. *Obstet Gynecol.* 2009 Feb;113(2 Pt 1):367-73.

Drahoradova et al., Longitudinal trends with improvement in quality of life after TVT, TTVT-O and Burch colposuspension procedures. *Med Sci Monit* 2011; 17(2)P:CR67-72.

Duckett et al., Pain after suburethral sling insertion for urinary stress incontinence. *Int Urogynecol J* 2013; 24:195-201.

Ek M, Altman D, Falconer C et al: Effects of anterior trocar guided-transvaginal mesh surgery on lower urinary tract symptoms. *Neurourol Urodyn.* 2010 Nov;29(8):1419-23.

Ek M, Tegeerstedt G, Falconer C et al: Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh. *Neurourol Urodyn.* 2010 Apr;29(4):527-31. Elmer C, Falconer C, Hallin A et al: Risk factors for mesh complications after trocar guided transvaginal mesh kit repair of anterior vaginal wall prolapse. *Neurourol Urodyn.* 2012 Apr 19. doi: 10.1002/nau.22231.

Elmer C, Blomgren B, Falconer C et al: Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. *J Urol.* 2009 Mar;181(3):1189-95.

Elmer C, Altman D, Engh M et al: Trocar-guided transvaginal mesh repair of pelvic organ prolapse. *Obstet Gynecol.* 2009 Jan; 113(1): 117-26.

Falagas M, Velakoulis S, Iavazzo C, et al. Mesh-related infections after pelvic organ prolapse repair surgery. *Eur J Obstet Gynecol Reprod Biol.* 2007 Oct; 134(2): 147-56.

Farrell S, Dempsey T, Geldenhuys L: Histological examination of "fascia" used in colporrhaphy. *Obstet Gynecol.* 2001 Nov;98(5 Pt 1):794-8.

Fatton R, Amblard P, Debodinance P. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)--a case series multicentric study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jul; 18(7):743-52.

Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol.* 2010 Feb;115(2 Pt 1):325-30.

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary

Incontinence.

<http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm>

Feng et al., Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients. *Int Urogynecol J* 2008; 19:1423-1427.

The Federal and Drug Administration. Urogynecological surgical mesh: Update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse. July 2011.
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>

Firoozi F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. *Urology*. 2010 Jan;75(1):203-6.

Foon R, Tooze-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Dec; 19(12): 1697-706.

Gangam N, Kanee A: Retroperitoneal hemorrhage after a vaginal mesh prolapse procedure. *Obstet Gynecol.* 2007 Aug; 110(2 Pt 2):463-4.

Ganj F, Ibeau O, Bedestani A et al: Complication of transvaginal monofilament polypropylene mesh in POP repair. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009 Aug;20(8):919-25. Epub 2009 Apr 7.

Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery* Vol 193, Issue 4, April 2007, p538-542.

Gauruder-Burmester A, Koutouzidou P et al: Effect of vaginal polypropylene mesh implant on sexual function. *Eur J Obstet Gynecol Reprod Biol.* 2009 Jan;142(1):76-80.

Groutz et al., Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure. *Journal of Women's Health* 2011;20(10):1525-1528.

Hamilton B, McCrery R: Dyspareunia and mesh erosion after vaginal mesh placement with a kit procedure. *Obstet Gynecol* 2008, 4:969-975.

Hazewinkel et al., Persistent groin pain following a trans-obturator sling procedure for stress urinary incontinence: a diagnostic and therapeutic challenge. *Int Urogynecol J* 2009; 20:363-365.

Hilger W, Walter A, Zobitz M et al: Histological and biomechanical evaluation of implanted graft materials in a rabbit vaginal and abdominal model. *Am J Obstet Gynecol* 2006; 195:1826-31.

Hinoul et al., Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O). *Int Urogynecol J* 2007; 18:1201-1206.

Hinoul P, Ombelet W, Matthe P et al: A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh kit (Prolift Anterior) for symptomatic cystocele repair. *J Minim Invasive Gynecol* 2008;15(5):615-620.

Hiltunen R, Takala, T, Heiskanen E et al: Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. *Obstet Gynecol*. 2007 Aug; 110(2 Pt 2):455-62.

Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3-15.

Iglesia C, Sokol A, Sokol E, et al. Vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol*. 2010 Aug;16(2 Pt 1):293-303.

Ignjatovic I, Stosic D: Retrovesical hematoma after anterior Prolift procedure for cystocele correction. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007 Dec;18(12):1495-7. Epub 2007 Jun 29.

Jacquetin B, Cosson M, Luente V et al: Prospective clinical assessment of the transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse-one year results of 175 patients. (Abstract #291: Presentation International Continence Society 2006).

Jacquetin B, Cosson M: Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009 Aug;20(8):893-6.

Jacquetin B, Patton B, Rosenthal C et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. *Int Urogynecol J* 2010 Dec;21(12): 1455-62.

Jacquetin B, Caquant F, Collinet P: Prolene Soft Mesh for POP surgical treatment - a prospective study of 264 patients. (ABSTRACT ONLY)

Jeffery S, Nieuwoudt A: Beyond the complications: medium-term anatomical, sexual and functional outcomes following removal of trocar-guided transvaginal mesh a retrospective cohort study. *Int Urogynecol J*. 2012 Apr 20. Epub ahead of print.

Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. *BJOG* 2008 Oct; 115(11):1350-61.

Kasturi S, Diaz S, McDermott C et al: De novo stress urinary incontinence after negative prolapse reduction stress testing for total vaginal mesh procedures: incidence and risk factors. *Am J Obstet Gynecol*. 2011 Nov;205(5):487.e1-4. EPub 2011 Jul 20.

Khandwala S, Jayachandran C: Transvaginal mesh surgery for pelvic organ prolapse- Prolift + M: a prospective clinical trial. *Int Urogynecol J*. 2011 Nov;22(11): 1405-11.

Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. *Eur J Surg*. 1999 Jul;165(7):665-73.

Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. *J. Surgical Research* 103, 208-214 (2002).

Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965-969, December 1998

Klinge U, Klosterhalfen M: Modified classification of surgical imeshes for hernia repair based on the analysis of 1,000 explanted meshes. Hernia. 2012 Jun;16(3):251-8. Epub 2012 May 5.

Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec; 19(24):2235-46.

Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.

Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1): 103-17.

Krambeck A, Dora C, Elliott D. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. Urology. 2006 May;67(5):1105-10.

Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. Aust NZ J Obstet Gynaecol. 2006 Feb;46(1):42-5.

Krause H, Bennett M, Forwood M. Biomechanical properties of raw meshes used in pelvic floor reconstruction. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec; 19(12): 1677-81.

Krlin R, Murphy A, Goldman H: Pro: the contemporary use of transvaginal mesh in surgery for pelvic organ prolapse. Curr Opin Urol. 2012 May 19. [Epub ahead of print]

Landsheere L, Ismail S, Lucot J et al: Surgical intervention after transvaginal ProLift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7.

LaSala C, Schimpf M: Occurrence of Postoperative hematomas after prolapse repair using a mesh augmentation system. Obstet Gynecol. 2007 Feb; 109(2 Pt 2):569-72.

Lawndy S, Withagen M, Kluivers et al: Between hope and fear: patient's expectations prior to pelvic organ prolapse surgery. Int Urogynecol J (2011) 22: 1159-1163.

Letouzey V, Deffieux X, Gervaise A et al: Transvaginal cystocele repair using a tension-free polypropylene mesh: more than 5 years of follow-up. Eur J Obstet Gynecol Reprod Biol. 2010 Jul;151(1):101-5.

Lo et al., Predictors for de novo stress urinary incontinence following extensive pelvic reconstructive surgery. Int Urogynecol J 2015; 26:1313-1319.

Lopes E, Lemos N, Carramao S et al: Transvaginal polypropylene mesh versus sacrospinous ligament fixation for the treatment of uterine prolapse: 1-year follow-up of a randomized controlled trial. Int Urogynecol J. 2010 Apr;21(4):389-94.

Lowder JL, Park AJ, Ellison R et al. The role of apical vaginal support in the appearance of anterior and posterior vaginal prolapse. *Obstet Gynecol.* 2008 Jan; 111(1): 152-7.

Lowman J, Jones L, Woodman P: Does the Prolift System cause dyspareunia? *Am J Obstet Gynecol.* 2008 Dec; 199(6):707.el-6.

Lucente V, Hale D, Miller D et al: A clinical assessment of Gynemesh PS for the repair of pelvic organ prolapse (POP). (POSTER PRESENTATION ONLY)

Lucente V, Milani A, VanDrie D et al: A lightweight mesh for transvaginal mesh repair- interim 3 month results. (ABSTRACT ONLY)

Lucente V, Molden, S, Barker, M, Karram, M, Point-Counterpoint: Transvaginal Placement of Synthetic Grafts to repair Pelvic Organ Prolapse, Current Bladder Dysfunction Reports, 2008.

Lucente V, Jacquetin B, Miller D, et al: Tranvaginal Mesh (TVM) An innovative approach to placing synthetic mesh transvaginally for surgical correction of pelvic support defects--perioperative safety results. (ABSTRACT AND VIDEO SUBMISSION ONLY)

Lucente V, Miller D, Babin B: Prospective clinical assessment of the Total Vaginal Mesh (TVM) technique for treatment of pelvic organ prolapse (POP) 6 &12 month results. (ABSTRACT ONLY)

Luciani A, Rapp D, Gong E et al: The surgical technique and early postoperative complications of the Gynecare Prolift pelvic floor repair system. *Can J Urol.* 2008 Apr; 15(2):4004-8.

Mamy L, Letouzey V, Lavigne J, et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J.* 2011 Jan;22(1): 47-52.

Marchionni M, Bracco G, Checcucci V: True incidence of vaginal vault prolapse. Thirteen years of experience. *J Reprod Med.* 1999 Aug;44(8):679-84.

Margulies R, Lewicky C, Dee Fetal: Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol* 2008; 199:678.el-678.e4.

Martan A, Svabik K. et al. Incidence and prevalence of complications after urogynecological and reconstructive pelvic floor surgery. *Ceska Gynekol.* 2007 Dec;72(6):410-5.

Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. *BJOG.* 2005 Jan;112(1):107-11.

Milani A, Withagen M, Vierhout M: Trocar-guided total tension-free vaginal mesh repair of post-hysterectomy vaginal vault prolapse. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009 Oct;20(10):1203-11.

Milani A, Hinoul P, Gauld J, Casson M, Prolift+M Investigators: Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcome. *Am J Obstet Gynecol.* 2011 Jan;204(1):74.el-8. Epub 2010 Oct 20.

Milani R, Withagen M, The H et al: Sexual function following trocar-guided mesh or vaginal native tissue repair in recurrent prolapse: a randomized controlled trial. *J Sex Med.* 2011 Oct;8(10):2944-53.

Miller D, Lucente V, Babin E et al: Prospective clinical assessment of the transvaginal mesh technique treatment of pelvic organ prolapse - 5-year results. *Female Pelvic Med Reconstr Surg.* 2011 May; 17(3): 139-43.

Mokrzycki M, Hampton B: Pelvic arterial embolization in the setting of acute hemorrhage as a results of the anterior Prolift Procedure. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jul;18(7):813-5.

Montoya et al., Anatomic relationships of the pudendal nerve branches. *AmJ Obstet Gynecol* 2011;205:504.e1-5.

Mostafa et al., A multicentre prospective randomised study of single-incision mini-sling (Ajust) versus ten ion-free vaginal tape-obturator (TVT-O) in the management of female stress urinary incontinence: pain profile and short-term outcomes. *European Journal of Obstetrics and Gynecology and Reproductive Biology* 2012; 165:115-121.

Murphy M, Sternschuss G, Haff R, van Raalte H, Lucente V: Quality of life and surgical satisfaction after vaginal reconstructive vs. obliterative surgery for the treatment of advanced pelvic organ prolapse. *Am J Obstet Gynecol.* 2008 May;198(5):573.el-7.

Murphy (Lucente, Goldman) - Time to rethink: an evidence-based response from pelvic surgeons to the FDA safety communication: "Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse." *Int Urogynecol J* (2012) 23:5-9.

Natale, F, La Penna C, Padoa A et al: A prospective randomized controlled study comparing Gynemeshfi, a synthetic mesh, and Pelvicolfi, a biologic graft, in the surgical treatment of recurrent cystocele. *Int Urogynecol J* (2009) 20:75-81.

Nieminen K, Hiltunen R, Takala T, et al. Outcomes after anterior wall repair with mesh: a randomized controlled trial with a 3 year follow-up. *Am J Obstet Gynecol.* 2010 Sep;203(3):235.

Nieminen K, Hiltunen R, Heiskanen E et al: Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Dec;19(12):1611-6.

Nyguen J, Burchette R. Outcomes after anterior vaginal prolapse repair: a randomized controlled trial. *Obstet Gynecol.* 2008; 111(4):891-8.

Olsen A, Smith V, Bergstrom J: Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol.* 1997 Apr;89(4):501-6.

Ostergard D: Polypropylene vaginal mesh grafts in gynecology. *Obstet Gynecol.* 2010 Oct; 116(4):962-6.

Pacquee S, Palit G, Jacquemyn Y: Complications and patient satisfaction after transobturator anterior and/or posterior tension-free vaginal polypropylene mesh for pelvic organ prolapse. *Acta Obstet Gynecol Scand.* 2008;87(9):972-4.

Pandit A, Henry J. Design of surgical meshes - an engineering perspective. *Technol Health Care.* 2004;12(1):51-65.

Paplomata E, Balaxix D, Pantelis T et al: Genital floor repair using polypropylene meshes: a comparative study. (ABSTRACT ONLY)

Roy S, Mohandas A, Coyne K et al: Assessment of the psychometric properties of the short-form prolapse/urinary incontinence sexual questionnaire (PISQ-12) following surgical placement of Prolift+M: A transvaginal partially absorbable mesh system for the treatment of pelvic organ prolapse. *J Sec Med* 2012;9: 1190-1199.

Tunn R, Picot A, Marschke J, et al: Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. *Ultrasound Obstet Gynecol* 2007; 29:449-452.

Parnell et al., Genitofemoral and perineal neuralgia after transobturator midurethral sling. *Obstetrics and Gynecology* 2012;119:428-31.

Pierce L, Grunlan M, Hou Y et al: Biomechanical properties of synthetic and biologic graft material following long-term implantation in the rabbit abdomen and vagina. *Am J Obstet Gynecol.* 2009 May;200(5):549.e1-8.

Reisenauer C, Kirshniak A, Drews U et al: Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. *Eur J Obstet and Gynecol Repr Biol* 2007;131:214-25.

Rosch R, Junge K, Holzl Fetal (2004) How to construct a mesh. In: Schumpelick V, Nyhus LM (eds) *Meshes: benefits and risks.* Springer, Berlin, pp 179-184.

Rosengren A, Bjursten L., Pore size in implanted polypropylene filters is critical for tissue organization. *J Biomed Mater Res A.* 2003 Dec 1;67(3):918-26.

Rubod C, Boukerrou M, Brieu M et al: Biomechanical properties of vaginal tissue: preliminary results. *Int Urogynecol J* (2008) 19:811-816.

Seker D, Kulacoglu H. Long-term complications of mesh repairs for abdominal wall hernias. *J Long Term Eff Med Implants.* 2011;21(3):205-18.

Shek D, Dietz H, Rane A et al: Transobturator mesh for cystocele repair. a short to medium term follow up using 3D/4D ultrasound. *Ultrasound Obstet Gynecol.* 2008; 32:82-86.

Silva WA, Treatment of stress urinary incontinence - midurethral slings: top-down, bottom-up, "outside in," or "inside-out." *Clinical Obstetrics and Gyencology* 2007; 50(2):362-375.

Simon M, Debodinance P: Vaginal prolapse repair using the Prolift Kit: a registry of 100 successive cases. *Eur J Obstet Gynecol Reprod Biol.* 2011 Sep;158(1):104-9.

Sivaslioglu A, Unlubilgin E, Dolen I. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocele. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Apr;19(4):467-71.

Song Y, Ye P, Hong X et al: Changes in levator ani muscle after vaginal hysterectomy and prolapse repair using total Prolift. *Int J Gynaecol Obstet.* 2009 Jul; 106(1):53-6. Epub 2009 Apr 8.

Srikrishna S, Robinson D, Cardozo L: A longitudinal study of patient and surgeon goal achievement 2 years after surgery following pelvic floor dysfunction surgery. *BJOG.* 2010 Nov; 117(12):1504-11.

Srikrishna S, Robinson D, Cardozo L, et al: Experiences and expectation of women with Urogenital prolapse: a quantitative and qualitative exploration. 2008. *BJOG* 115:1362-1368

Su T, Lau H, Huang W et al: Short term impact on female sexual function of pelvic floor reconstruction with the Prolift procedure. *J Sex Med.* 2009 Nov;6(11):3201-7.

Takeyama M, Koyama M, Murakami Get al: Nerve preservation in the tension free vaginal mesh procedures for pelvic organ prolapse - a cadaveric study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Apr;19(4):559-66. Epub 2007 Oct 10.

Tamussino K, Hanzal E, Kolle D et al: Tension-free vaginal tape operation: results of the Austrian Registry. *Obstet Gynecol.* 2001 Nov;98(5 Pt 1):732-6.

Franco and Tardiu, Contrasure-Needleless single incision sling compared with transobturator TVT-O for the treatment of stress urinary incontinence: long term results. *Int Urogynecol* (2015) 26:213-218.

Timmer M: Technical note - Evaluation of Mesh contraction in a swine fascia Implantation Model. (ABSTRACT ONLY)

Tommaselli et al., Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow up. *Int Urogynecol J* 2010; 21:1211-1217.

Touboul - Major Venous Hemorrhagic Complication during Transvaginal cystocele repair using the transobturator approach.

U.S. Preventive Services Task Force (August 1989). Guide to clinical preventive services: report of the U.S. Preventive Services Task Force. DIANE Publishing. pp. 24-. ISBN 978-1-56806-297-6.

Vakili B, Trang H, Loesch H et al: Outcomes of vaginal reconstructive surgery with and without graft material. *American Journal of Obstetrics and Gynecology* (2005) 193:2126-32.

Van Raalte H, Lucente V, Molden S, et al: One-year anatomic and quality-of-life outcomes after the Prolift procedure for treatment of post-hysterectomy prolapse. *Am J Obstet Gynecol.* 2008 Dec;199(6):694.e1-6.

Velemir L, Amblard J, Patton B et al: Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. *Ultrasound Obstet Gynecol.* 2010 Apr;35(4):474-80.

Vierhout M, Withagen M, Putterer J: Rectal obstruction after a vaginal posterior compartment polypropylene mesh fixed to the sacrospinous ligaments. Int Urogynecol J (2011) 22:1035-1037.

Walid MS, Heaton RL: Laparoscopic apical mesh excision for deep dyspareunia caused by mesh banding in the vaginal apex. Arch Gynecol Obstet. 2009 Sep;280(3):347-50.

Wall L, Brown D: The perils of commercially driven surgical innovations. Am J Obstet Gynecol. 2010 Jan;202(1):30.e1-4. Epub 2009 Jul 15.

Waltregny et al., TTVT-O for the treatment of female stress urinary incontinence: results of a prospective study after a 3-year minimum follow-up. European Urology 2008; 53:401-410.

Weber AM, Abrams P, Brubaker L, The Standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J (2001)12: 178-186.

Weber AM, Walters MD, Piedmonte MR, et al: Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001 Dec;185(6):1299-304; discussion 1304-6.

Withagen M, Vierhout M, Hendricks J, et al: Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedures. Obstet Gynecol. 2011 Sep;118(3):629-36.

Zyczynski H, Carey M, Robinson D, Sikirica V, et al: One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. (ABSTRACT ONLY presentation American Urological Association, 2009 and International Urogynecological Association meeting 2009).

CORPORATE DOCUMENTS:

ETH-00002.

ETH-00005.

ETH-00006.

ETH-00252 Gynemesh Patient Brochure.

ETH-00256.

ETH-00260.

ETH-00293.

ETH-00929-0030.

ETH-00943

ETH-00986 Device Descriptions Similarities.

ETH-01032.

ETH-01039.

ETH-01074-01235.

ETH-0118.

ETH-01120.

ETH-01121.

ETH-01242 Dec 20 2007 letter to Ethicon.

ETH-01292.

ETH-01322.

ETH-01761-01769.

ETH-01762.

ETH-01764.

ETH-01777.
ETH-02325.
ETH-02601.
ETH-02683-02696.
ETH-03231.
ETH-03560.
ETH-07156.
ETH-00011724.
ETH-17369.
ETH-17621.
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ETH-18935
ETH-47351.
ETH-47352.
ETH-47353.
ETH-48281.
ETH-48769.
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ETH-60142.
ETH-60173.
ETH-60554.
ETH-71304.
ETH-71307.
ETH-77061.
ETH-80249.
ETH-80265.
ETH-80270.
ETH-80271-08272.
ETH-80297.
ETH-80303.
ETH-80308.
ETH-80318.
ETH-80636-80644.
ETH-80643 Complications.
ETH-80645-80651.
ETH-80656.
ETH-82320.
ETH-82419.
ETH-87999.
ETH-00005.
ETH-00386.
eth.mesh.00035379.
ETH-00253.
ETH-00255-000258 Ethicon Marketing Brochure
ETH-00264
ETH-00382
ETH-00383
ETH-00384
ETH-00385
ETH-00797-00927
ETH-00933-00934
ETH-01321
ETH-01363-01365
ETH-01624

ETH-01643	
ETH-01671	Prolift IFU
ETH-02707-02708	
ETH-02709	
ETH-02711	
ETH-02713	
ETH-02794	
ETH-02813	
ETH-03260-03271	Prolift Product Description Document.
ETH-03272-03419	Prolift Design Requirements Matrix.
ETH-03281	
ETH-03420-03479	Prolift design & development.
ETH-03430	
ETH-03480-03530	Concept DDSA.
ETH-03531-03567	Final DDSA.
ETH-03568-03578	Design failure modes effects analysis.
ETH-03579-03876	Development Completion Report.
ETH-03611	
ETH-03650	
ETH-03672	
ETH-03747	
ETH-03767	
ETH-04022-04068	Material Specifications.
ETH-04069-04355	test methods.
ETH-04240-03479	Prolift Design & Development Plan overview, design input, history,
biocompatibility	
ETH-04356-04714	Test methods validation.
ETH-04715-05138	Test methods validation.
ETH-05139-05143	Supplier Status.
ETH-05144-05145	Process map.
ETH-05146-05199	Operational equipment summary.
ETH-05200-05503	Operational equipment summary.
ETH-06019-06025	Finished good specifications.
ETH-06026-06029	Process specifications.
ETH-06229-06256	Content of surgical technique document and IFU.
ETH-06635-06641	Guide documents.
ETH-07152-07158	Clinical expert report.
ETH-07304-07310	
ETH-07427-07433	
ETH-07434-07494	
ETH-07495-07545	
ETH-07546-07609	
ETH-07712	Ethicon advertisement.
ETH-08028.	
ETH-16986	IFU Statement.
ETH-17061	IFU Statement.
ETH-19622	
ETH-19645	
ETH-19943	Hydrodissection description.
ETH-19944	
ETH-19945	
ETH-48130	
ETH-49659	
ETH-60102	
ETH-60136	
ETH-60142	
ETH-60149	
ETH-60151	
ETH-62214	
ETH-62799	

ETH-62803 Revised IFU.
ETH-65876 Original Prolift IFU.
ETH-70371
ETH-70373
ETH-74435
ETH-76140
ETH-76182
ETH-76690
ETH-076774
ETH-80289
ETH-80640
ETH-80641
ETH-80643 Complications.
ETH-80657
ETH-80660
ETH-83193
ETH-83318
ETH-83323
ETH-83452
ETH-83788
ETH-85678 Email from Butrick to Robinson.
ETH-00386
ETH.MESH.00419571-00419600 Prolift Technique
ETH.MESH.00419572
ETH.MESH.00419573
ETH.MESH.00419575
ETH.MESH.00419576
ETH.MESH.00419578
ETH.MESH.00419579
ETH.MESH.00419582
ETH.MESH.00419584
ETH.MESH.00419585
ETH.MESH.00067356-00067363 Lucente Webinar Transcription
EWHU website
01-27-09 Email from Maroulis Jones.pdf
ETH-18951.pdf
ETH-18953.pdf
ETH-18963 Meeks.pdf
ETH-18967-18975.pdf
ETH-60136-60137.pdf
ETH-60136.pdf
ETH.MESH.00008039.pdf
Eth.mesh.00008041-00008042.pdf
Eth.mesh.00008043-00008112.pdf
Eth.mesh.00126954.pdf
ETH.MESH.02010835
ETH.MESH.00869977
ETH.MESH.02589032-ETH.MESH.02589079
ETH.MESH.00126954
1/27/09 email from Maroulis to Jones
ETH-60136-60137
ETH.MESH.00008043-00008112
ETH-18967-18975
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ETH-18761-18763

ETH-83454-83455

ETH.MESH.00000272

ETH-80645-80651

ETH-76139

ETH-76140-76145

ETH.MESH.00011731-00011736

ETH-01383-01398

ETH-00940-00944

ETH.MESH.00126755 - 00126757

May 15, 2000 letter from FDA to Ethicon

510 (k) Application

ETH.MESH.00062770-00062789 (Clinical Data Synopsis: Prolift)

ETH.MESH.00870466-0080475 Expert meeting with Klasterhalfen 2006

ETH.MESH.02010834-0201855 Biomechanical consideration for pelvic floor mesh design

ETH.MESH.03719177-03719195

Vailhe focus on exposure Road to Improvement 10-14-11

ETH.MESH.00570955-00570956 Prolapse mesh explants 6-2009

ETH.MESH.02017152-02017158 2-23-07 Expert Meeting

ETH.MESH.00006636 Klosterhalfen Interim report mesh explants pelvic floor

ETH.MESH.02589032-02589079 PA Consulting Group Investigating Mesh erosion in pelvic floor.

ETH.MESH.00869977-00870098 Peter A Meier (Principal Scientist J&J) Clinical evaluation report on mesh review.

ETH-18906-18920 (Study abstracts)

ETH-00986-00990 (Device Descriptions and Similarities)

ETH-18935-18950 (Design Validation Protocol)

ETH-00252-00265 (Marketing materials)

Regional Meeting documents

ETH-18976-19660 (Pelvic Organ Prolapse Surgery, a presentation by David B. Robinson, MD)

ETH.MESH.02341454-459 ETH.MESH.00870466

ETH.MESH.01782867 ETH-77061

ETH.MESH.00081478

ETH.MESH.00329334: June 30, 2006 email from Meng Chen to Mark Yale re: The Feedback from the Medical Directors for the IFU updates

ETH.MESH.00329335-36

ETH-80643

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NEW IFU

Original IFU.

Prolift Clinical Data Synopsis.

Southern Midwest Regional Meeting

06/07/08 email from St. Hilaire to Maher & Jones

Parisi Testimony re: changes to IFU's or Prof. ED materials since new warnings/IFU's

Parisi testimony re changes to IFU's or Prof ED Materials since new warnings updates.pdf

EXHIBIT "D"

KROPF, DIANE (Date of Birth: Feb 10, 1944)

MESH PROBLEMS

Nov 16, 2015

HISTORY / PHYSICAL

PQRS DOCUMENTATION:

Date Current Medications Verified 11/16/2015. List of current medications (includes prescription, over-the-counter, herbals, vitamin/mineral/dietary [nutritional] supplements) documented by the provider, including drug name, dosage, frequency and route.

Documentation that Pneumococcal vaccine administered or previously received.

BMI Screening and Follow-Up - reported on this patient 11/16/2015. Calculated BMI below normal parameters and a follow-up plan was documented.

PQRS tobacco reported on this patient 11/16/2015.

Patient screened for tobacco use. Current non-user.

PRESENT ILLNESS: The patient is a 71 year old White female who presents today for a new patient visit. Family of patient is present in the examination room. Patient specifically stated that any discussion concerning her medical condition can be discussed with the family member(s) present: husband.

Mrs. Kropf is here for complications with vaginal mesh.

In the past, she has had 3 pregnancies and 3 vaginal deliveries. The first labor was 23 hours, the second was breach and the third had a "cord around her neck". She does not recall any forceps used or lacerations involving her rectum. She did tear "quite a bit" with the breached delivery.

She has had back pain due to a sacral fracture and multiple issues for years. She has had disc spacers from L4-S1 without change in back pain. That kind of pain has nothing to do with the type of pain that she is having since the vaginal mesh.

She reports that the bladder problems started years (about 20 years) after the vaginal deliveries.

Her urinary symptoms worsened in the late 2000's that she describes as worsening urinary frequency, urgency, and incontinence. She tried some medicines, but they did not help very much. She was "disgusted" by a vaginal bulge and wanted it corrected. She was hoping the prolapse correction would help her bladder. It did not give her pain.

Urodynamics preoperatively did not show an overactive bladder nor ISD. She believes she was offered a Pessary and exercises, but she wanted her problem "fixed".

She had vaginal hysterectomy, Prolift anterior with TTV for urethral hypermobility (G3 cystocele, G2 rectocele) in April 2010. She initially was happy to not have the bulge there. Even her urinary frequency improved for a few months, then it started to get worse by 2011. She was found to have "granulation tissue" around May 2010 requiring silver nitrate treatment 6 months after. "I kept on bleeding".

In the ensuing years, she had difficulty controlling the pain after the operation and had issues with pain medications, "trying to get the pain under control".

By March 18, 2013, the mesh was exposed and found during intercourse by her husband who was having excoriations on his penis. No mesh was excised. She was started on topical estradiol vaginal 9/30/2013. In 11/11/2014, she had explantation of a left extruded vaginal mesh band due to persistent bleeding and pain. She does not feel that this helped and wonders why they did not take all of the mesh out.

She has not been sexually active since the initial vaginal mesh extrusion around March 2013. He reports penile abrasions and pain if he tries to have sex with her.

"Knowing what I know now, I would absolutely not ever have this again".

Just sitting there, she describes her pain as 0-1/10. If she gets up to walk, it is a 7/10 pain. The pain is vaginal and in her inner thighs. Her husband chimes in and feels that "they injured her pudendal nerve".

She is bothered to squat on the toilet outside of her house (does not want to sit on dirty commode), she cannot empty well and the "urine runs down my legs". She is bothered by her abdominal girth and weight gain since her mesh surgeries. She feels she cannot be active due to the pain.

She has chronic constipation. She used Miralax almost daily with improvement until stopping her regimen. She uses a suppository or Fleet's for breakthrough. She can urinate every 2 hours during the day. She has nocturia 1 x without enuresis. She does wear a pad at night. She rarely uses a pad during a day. Her urination is "under control now" other than the positional issues with voiding. She wishes she did not have pain and did not urinate "all down her legs" since the mesh placements. She wishes she could some day have sex again.

ACTIVE MEDICATIONS:

Date medications last reviewed with patient: 11/16/15

Foltanx Vitamin B Complex oral tablet, # once a day

Lisinopril - 5 mg oral tablet 10 mg oral tablet, # once a day

Morphine Sulfate 15 mg oral tablet, # three times a day

Topamax 100 mg oral tablet, # once a day

TraZODone Hydrochloride 100 mg oral tablet, # once a day

ALLERGIES:

Date patient last asked about allergies: 11/16/15

Medication Allergies: NKDA

Environmental Allergies: DUST, POLLEN, TREES

PFSH: Updated - 11/16/2015

PAST MEDICAL HISTORY: Anemia, Hypertension, Allergies, Constipation, Diarrhea, GERD, Hemorrhoids, Bladder Infection, Hematuria, Menopause, Arthritis, Back Pain, Fibromyalgia, Anxiety, Chronic Fatigue Syndrome, Depression, Asthma, Bronchitis, Pneumonia

PAST SURGICAL HISTORY: Laminectomy 2004, Cholecystectomy 2007, Cystoscopy 2012, Hysterectomy 2010, Unilateral Oophorectomy 2010, Facial Surgery 1985, Nasal Surgery 1965, Tonsil Surgery (T and A), Back Surgery 2004, foot surgery

FAMILY HISTORY:

Arthritis - Father, Mother

Depression- Mother

High Blood Pressure - Mother, Sister, Son

Kidney Disease - Sister

Tuberculosis - Grandmother

SOCIAL HISTORY:

Marital Status: Married

Daily Alcohol Consumption: occasional-social

Does not smoke or use any tobacco products.

Caffeine Use: low

Travel History: There is a history of travel to Mexico.

REVIEW OF SYSTEMS: Updated - 11/16/2015

Constitutional: Fatigue.

Gastrointestinal: Abdominal Pain.

Musculoskeletal: Arthritis, Back pain, Joint pain, Muscle Weakness, Neck Pain/Stiffness.

Ear/Nose/Throat/Mouth: Congestion, Sinus Problems.

Genitourinary: Back Pain, Flank Pain, Nocturia.

Other than noted above, all other systems negative

Vital Signs:

11/16/2015: BP Systolic: 134, BP Diastolic: 76, Pulse: 70, Height: 61", Weight: 128 lbs, BMI: 24.183, BMI Plan: Yes

PHYSICAL EXAMINATION:

CONSTITUTIONAL:

General Appearance: Well developed, well nourished White female in no acute distress.

Eyes: pupils and irises - lens transparent, without opacities or scars, sclera - sclera not edematous, not injected, not icteric.

RESPIRATORY: Normal respiratory effort without labor. No wheezing.

ABDOMEN: The liver and spleen appear to be normal. Abdomen is **obese**. Abdomen **distended**. Abdominal scars are well-healed. No abdominal masses or tenderness noted.

GENITOURINARY:

Kidneys: No CVA tenderness area of left kidney. No CVA tenderness area of right kidney.

Urethral Meatus: The meatus appears to be normal in size. A 3 mm caruncle is noted. The meatus is atrophic.

Urethra: There is no urethral hypermobility. Q-tip test is negative.

Pelvic Examination:

POP-Q

Catheter Residual: 10 ml Urine clear

Measurements:

Aa: -3cm

Ba: -3cm

C: -5cm

gh: +4cm

pb: +3cm

tvL: +7cm

Ap: 0cm

Bp: 0cm Uterus and cervix are surgically absent. Anus and perineum normal, with good sphincter tone.

External Genitalia: Atrophic external genitalia

Vagina: No cystocele present. A grade 2 rectocele is present. No splinting to empty bowels. She has a vaginal mesh EXTRUSION of the left proximal Prolift arm and cuff. A 5mm x 10mm area is exposed and friable; this bleeds easily. The lateral attachment into the pelvic side wall is tender (moderately) to palpation. There is less banding on the right, but it is also compatible with likely mesh contracture; no right sided banding has extruded.

She has significant atrophy around her introitus, especially posteriorly. There is no clear lichen sclerosis et atrophicus.

Nurse present for pelvic examination.

MUSCULOSKELETAL: Gait appears normal.

NEUROLOGICAL: Patient appears to be well oriented to time, place, and person.

LYMPHATICS: There are no abnormal nodes palpated in either inguinal area.

ASSESSMENT AND PLAN

Results received through this encounter (11/16/15)

None

Historical results

None

Vital Signs:

11/16/2015: BP Systolic: 134, BP Diastolic: 76, Pulse: 70, Height: 61", Weight: 128 lbs, BMI: 24.183, BMI Plan: Yes

Urinalysis Automated (81003-QW):

11/16/2015: Color: YELLOW, Clarity: CLR, Glucose: NEG, Bilirubin: NEG, Ketone: NEG, Specific Gravity: 1.020, Blood: NEG, pH: 7.0, Protein: NEG, Urobilinogen: 0.2, Nitrite: NEG, Leukocytes: NEG, Collection Method: Clean Catch

PROBLEM LIST:

Dyspareunia (ICD9: 625.0, ICD10: N94.1): New With Added Workup

CURRENT IMPRESSION:

Erosion of implanted vaginal mesh and other prosthetic materials to surrounding organ or tissue, initial encounter (ICD9: 629.31, ICD10: T83.711A): New With Added Workup
Pelvic and perineal pain (ICD9: 625.9, ICD10: R10.2): New With Added Workup
Postmenopausal atrophic vaginitis (ICD9: 627.3, ICD10: N95.2): New With Added Workup
Rectocele (ICD9: 618.04, ICD10: N81.6): New With Added Workup

DISCUSSIONS:

Topical Estrogen Therapy Review:

Discussed at length the benefits and risks of topical estrogen therapy. I explained the relationship of any estrogen therapy with breast cancer. The decision to use or not use was a joint decision made by me and the patient with consideration to her health risks.

NEW PLAN OF TREATMENT:

Ordered

Lab - Urine Culture & Sensitivity - Ordered 11/16/15

Cath specimen

Schedule: Today

MU - Educational Material - Ordered 11/16/15

Disease Specific Pamphlet given to patient

MU - Patient Summary of Care Record Provided - Ordered 11/16/15

Completed by Provider

None

PATIENT SUMMARY: She has dyspareunia, vaginal and abdominal pain related to extrusion and contraction of Prolift vaginal mesh. We discussed the diagnosis and management options.

Vaginal pain and dyspareunia: I recommend excision of extruded mesh and tight mesh contractures of the proximal Prolift arms. This will improve vaginal wall mobility and hopefully allow her to have sex, again. However, the pain may persist and prolapse may recur. I also recommend that she comply with the topical estradiol therapy that was prescribed given her atrophy; improving the atrophy will help her heal better from any planned mesh revision.

For the rectocele: I explained that this is asymptomatic and needs no current therapy. However, add dietary fiber (20 grams a day), and avoid straining and constipation. No surgery is indicated for that at this time.

Discontinued Medications:

none

PRESCRIPTION THIS VISIT:

Date medications last reviewed with patient: 11/16/15

(The purpose of any medications prescribed on this visit, mode of administration, and side effects were discussed with the patient.)

INSTRUCTIONS/CODING DATA REVIEW:

Data:

I had an extensive counseling session with the patient concerning the diagnosis and treatment options.
I had an extensive discussion with the patient's family concerning the diagnosis and treatment.
I performed an extensive review and summary of the patient's medical records.

Patient Instructions:

Patient is instructed to call me at the office or contact my answering service if there is no improvement, or if the condition worsens.

CPT coding calculation based upon time.

(New Patient-Time)

60 or more minutes were spent face to face with this patient and/or her family. I spent greater than 50% of that time providing counseling and/or coordination of care. She and I discussed her diagnosis. I counseled her concerning **dyspareunia** and the various ways to manage the condition. I advised her of the prognosis concerning her options.

Electronically signed by: Ricardo R. Gonzalez, M.D. 11/17/2015 06:17:34 PM CST

Edited by: Erica Munoz 11/16/2015 11:27:21 AM CST

Edited by: Claudia Garcia 11/16/2015 11:35:56 AM CST

Encounter Notes

From User: 12claudiag

To User:
rgonzalez
Sent Date: 11/16/2015 11:32:14 AM CST
Patient:
KROPF, DIANE
Home Phone:
(540)846-2576
Work Phone:
(540)785-2706
Email:
JD2@COMCAST.NET
Priority:
Normal
Provider:
rgonzalez
Location:
1270-Powers
Notes:
Patient is in your office

Electronically Signed by: null 11/16/2015 11:32:14 AM CST